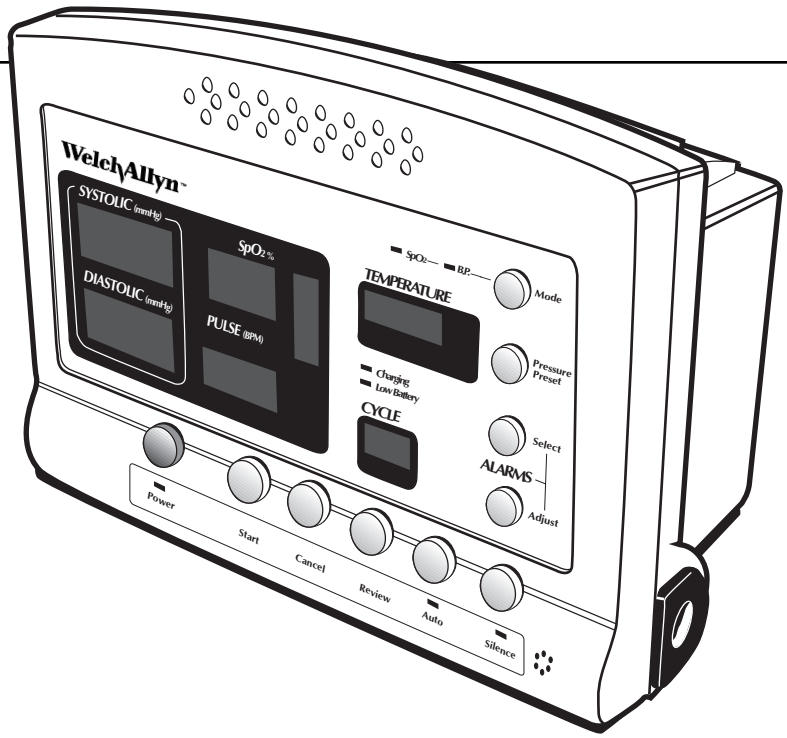
Manuals
Service Manual



Welch Allyn®

Vital Signs Monitor

Operator's Manual

CAUTION

United States Federal Law restricts this device to
sale by or on the order of a licensed health care practitioner.

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SECTION I
INTRODUCTION

1. About the Operator Manual
2. Product Overview
3. Indications/Contraindications For Use
4. Special Features
5. Supplies and Accessories

I. 1 ABOUT THE OPERATOR MANUAL

The operator manual is designed to help you understand the capabilities and operation of your Welch Allyn Vital Signs Monitor. The manual has six tabbed sections and the first page of each section outlines the contents so you can readily find the information you need.

The information included in this manual is inclusive of all options available with the Welch Allyn Vital Signs Monitor (ie. SpO_2, Temperature and Printer). **The applicability of some sections of this operator manual will depend on the configuration of your particular unit**.

The first two sections, INTRODUCTION and FUNCTIONS & SPECIFICATIONS introduce you to the product, its applications and its capabilities. The next two sections, SYSTEM INSTALLATION and OPERATING PROCEDURES takes you step by step through the installation and functional operation of the monitor in a logical sequence. The final two sections, TROUBLESHOOTING/MAINTENANCE/CALIBRATION and WARRANTY AND SERVICE INFORMATION are resources to offer troubleshooting or other special help as needed.

This information is intended as a comprehensive guide to the operation of the Welch Allyn Vital Signs Monitor. To achieve satisfactory results, the operator should read this manual thoroughly before attempting to use the monitor. A quick reference operator's guide is provided on the side of the monitor as a convenient reference for experienced operators.

I. 2 PRODUCT OVERVIEW

The Welch Allyn Vital Signs Monitor is designed to non-invasively and automatically measure systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) for adult and pediatric patients over the age of 3 years. All blood pressure, pulse, temperature and SpO_2 values are displayed on large, easy-to-read displays, and may be printed via an integrated thermal printer, as desired.

The rechargeable battery and wide variety of mounting accessories make the Welch Allyn Vital Signs Monitor convenient for many locations. The operator may choose any combination of simultaneous measurement modalities. This flexibility, combined with features such as programmable alarms and automatic blood pressure cycles, makes the Welch Allyn Vital Signs Monitor ideal for a wide variety of patient monitoring needs.

The Welch Allyn Vital Signs Monitor is intended for use in a wide variety of health care settings. This includes hospital departments, as well as patient transport within the hospital environment. The Welch Allyn Vital Signs Monitor is also intended for use in alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes. The Welch Allyn Vital Signs Monitor may also be used during patient transport within any of these alternate care environments.

The Welch Allyn Vital Signs Monitor is not intended for the monitoring of patients during transport external to the health care environment (eg. ambulance, helicopter transport). The Welch Allyn Vital Signs Monitor is not intended for use in environments which are not supervised by a health care practitioner.

I. 3 INDICATIONS/CONTRAINDICATIONS FOR USE

The Welch Allyn Vital Signs Monitor is intended for monitoring of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients, age 3 and above. The device is not designed, sold or intended for use except as indicated.

The monitor is not designed for use with neonates, infants or children under the age of 3 years.

The monitor should not be used on patients who are linked to heart/lung machines.

I. 4 SPECIAL FEATURES

The following special features enhance the use of the Welch Allyn Vital Signs Monitor:

Choice of Measurement Modalities

Non-invasive blood pressure, temperature, and SpO_2 measurements may be made independently or simultaneously.

Operator Selectable BP Measurement Intervals

Automatically takes BP measurements at intervals from 1 to 90 minutes. Special "STAT" mode allows continuous blood pressure measurements for up to 15 minutes.

Programmable Alarms

Both visual and audible alarms indicate readings outside of operator programmable high/low limits, and also indicate system hardware/software problems.

Non-Invasive, Oscillometric BP

Eliminates the risks associated with invasive monitoring, with no need for microphones or external transducers.

Prior Data Recall

Measurement data from up to 99 previous determinations is available at the touch of a button.

Operator-Friendly Results

Large, easy-to-read LED displays are complemented by an integrated thermal printer.

AC or Self-Contained Battery Power

The Welch Allyn Vital Signs Monitor is conveniently available in many locations, for a variety of monitoring needs, including interdepartmental transport within the facility.

I. 5 SUPPLIES AND ACCESSORIES

BLOOD PRESSURE ACCESSORIES AND SUPPLIES

5200-01 Cuff Assembly: Adult (cuff, bladder and connector)
5200-02 Cuff Assembly: Large Adult (cuff, bladder and connector)
5200-03 Cuff Assembly: Small (cuff, bladder and connector)
5200-10 Cuff Assembly: Extra-Large Adult (cuff, bladder and connector)

5082-59 Cuff: Adult
5082-61 Cuff: Large Adult
5082-63 Cuff: Small
5082-64 Cuff: Extra-Large Adult

5200-04 Bladder: Adult (includes connector)
5200-05 Bladder: Large Adult (includes connector)
5200-06 Bladder: Small (includes connector)
5200-11 Bladder: Extra-Large Adult (includes connector)

5200-07 Pressure Hose (8ft.) (2.4M) Note: One additional hose may be connected to provide extended length. All appropriate connectors are included.

5200-08 Calibration T-Connector

TEMPERATURE ACCESSORIES AND SUPPLIES

5200-20 Oral Probe: (9ft.) (2.7M)

5200-22 Rectal Probe: (9ft) (2.7M)

05031-101 Disposable Probe Covers (1000 covers, packaged 25/box)

06137-000 Temperature Calibration Key

01800-210 Model 9600 Temperature Calibration Kit, 110v

NONIN® PULSE OXIMETRY ACCESSORIES AND SUPPLIES

5200-40 Finger Clip Sensor with 9ft. (2.7M) cable
5200-54 Finger Clip Sensor with 3ft. (0.9M) cable
5200-41 Ear Clip Sensor
5200-42 Flex Sensor
5200-44 Reflectance Sensor
5200-45 Reflectance Sensor Holder (10)
5200-46 SpO_2 Adult Finger Flexiform Sensors (10)
5200-47 SpO_2 Pediatric Finger Flexiform Sensors (10)
5200-50 SpO_2 Sensor Attachment Tape
5200-51 SpO_2 Hydrogel Tape Strips
5200-52 SpO_2 Extension Cable (3ft) (0.9m)
5200-53 SpO_2 Finger Phantom Calibration Kit
5200-55 SpO_2 Extension Cable (9ft) (2.7m)

NELLCOR PURITAN BENNETT™ PULSE OXIMETRY ACCESSORIES AND SUPPLIES

DS-lOOA DURASENSOR® Adult Oxygen Transducer
EC-8 Extension Cable (8 ft.)
D-YS DURA-Y® Oxygen Transducer (1 sensor, 40 wraps)
D-YSE Ear Clip, (use with Dura-Y sensor)
D-YSPD PediCheck™ Pediatric Spot-Check (use with Dura-Y sensor)
D-25 OXISENSOR® II Adult Digit Oxygen Transducer (case of 24)
D-25L OXISENSOR® II Adult Digit Oxygen Transducer, long cable (case of 24)
D-20 OXISENSOR® II Pediatric Oxygen Transducer (case of 24)
I-20 OXISENSOR® II Infant Digit Oxygen Transducer (case of 24)
R-15 OXISENSOR® Adult Nasal Oxygen Transducer (case of 24)
OXICLIQ® A Adult Oxygen Transducer, use with OC-3 cable (case of 24)
OXICLIQ® P Pediatric Oxygen Transducer, use with OC-3 cable (case of 24)
OC-3 OXICLIQ® Sensor Cable
OXI-A/N OXIBAND® Adult/Neonatal Oxygen Transducer (1 sensor, 50 wraps)
OXI-P/I OXIBAND® Pediatric/Infant Oxygen Transducer (1 sensor, 50 wraps)
RS-10 Reflectance Oxygen Transducer (6 sensors, 6 headbands)
SRC-2 Portable Oximetry Tester

MOUNTING ACCESSORIES AND SUPPLIES

5200-60 COMPLETE MOBILE STAND UNIT includes:
Accessory Pack
Large Basket
Pole and Base Assembly
Recommended for Models: 52STP, 52STO, 52OTP, 52OTO, 52NTP, 52NTO

5200-61 MODIFIED MOBILE STAND UNIT includes:
Large Basket
Pole and Base Assembly
Recommended for Models: 52OOO, 52OOP, 52SOO, 52SOP, 52NOO, 52NOP

5200-62 COMPLETE WALL MOUNT UNIT includes
Accessory Pack
Large Basket
Wall Mount Bracket
Recommended for Models: 52STP, 52STO, 52OTP, 52OTO, 52NTP, 52NTO

5200-63 MODIFIED WALL MOUNT UNIT includes:
Large Basket
Wall Mount Bracket
Recommended for Models: 52OOO, 52OOP, 52SOO, 52SOP, 52NOO, 52NOP

5200-64 COMPLETE IV POLE MOUNT UNIT includes:
Accessory Pack
Large Basket
IV Pole Mount Bracket
Recommended for Models: 52STP, 52STO, 52OTP, 52OTO, 52NTP, 52NTO

5200-65 MODIFIED IV POLE MOUNT UNIT includes:
Large Basket
IV Pole Mount Bracket
Recommended for Models: 52OOO, 52OOP, 52SOO, 52SOP, 52NOO, 52NOP

5200-66 COMPLETE BED-RAIL MOUNTING UNIT includes:
Accessory Pack
(2) Bed-Rail Brackets
Recommended for Models: 52STP, 52STO, 52OTP, 52OTO, 52NTP, 52NTO

5200-67 MODIFIED BED-RAIL MOUNTING UNIT includes:
(2) Bed-Rail Brackets
Recommended for Models: 52OOO, 52OOP, 52SOO, 52SOP, 52NOO, 52NOP

5200-68 Cuff Clip
5200-69 Accessory Pack
5200-70 Anti-Theft Kit for Mounting Devices

MISCELLANEOUS SUPPLIES

7052-25 Printer Paper (6 rolls/box)
5200-80 AC Power Transformer (plug-in transformer) - North American Version
5200-81 AC Power Transformer (plug-in transformer) - European Version
5200-82 AC Power Transformer (plug-in transformer) - United Kingdom Version
5200-83 AC Power Transformer (plug-in transformer) - Australian Version
5200-84 Lead-acid Battery
5200-85E Operator Manual
5200-86E Service Manual
5200-88 Plastic Monitor Covers (pack of 5)
5200-100 Welch Allyn Vital Signs Monitor Carrying Case
5200-101 AC Power Transformer (desktop transformer, line cord not included) - North AmericanVersion
5200-102 AC Power Transformer (desktop transformer, line cord not included) - European Version
5200-103 AC Power Transformer (desktop transformer, line cord not included) - United Kingdom Version
5200-106 Transformer Mounting Kit (for use with the desktop transformer)
5200-110 Line Cord (United States/Canada/Japan version)
5200-111 Line Cord (European version)
5200-112 Line Cord (United Kingdom version)
5200-113 Line Cord (Australian version)
5200-114 Line Cord (Swiss version)
5200-115 Line Cord (South American version)

SECTION II
FUNCTIONS AND SPECIFICATIONS

1. Blood Pressure Operating Modes
    a. Max/Min Blood Pressure and Pulse Ranges
    b. Blood Pressure Manual Mode
    c. Blood Pressure Auto Mode

2. Temperature Operating Modes
    a. Max/Min Temperature Ranges
    b. Temperature Normal Mode
    c. Temperature Monitor Mode

3. SpO_2 Operating Mode
    a. Max/Min SpO_2 Ranges
    b. SpO_2 Monitor Mode

4. Pulse Rate Feature
    a. Max/Min Pulse Rate Ranges

5. Performance Specifications

6. Technical Specifications
    a. Mechanical Specifications
    b. Electrical Specifications
    c. Environmental Specifications

II. 1. BLOOD PRESSURE OPERATING MODES

When a blood pressure measurement cycle is initiated, the cuff will automatically inflate to the operator selected pressure level.

The cuff will immediately begin to deflate in a stepped fashion and will determine systolic pressure and diastolic pressure from the pulses sensed by the cuff at various pressure levels. This is the oscillometric method of non-invasive blood pressure monitoring.

Blood pressure measurements may be initiated manually, or automatically at time intervals determined by the user.

At the completion of a measurement cycle the systolic and diastolic pressures are displayed. If the Monitor is in Automatic Mode, the measured values are kept on display until the next BP measurement is initiated. When not in Automatic Mode, the measured values are displayed for two minutes, after which time the display screen is blanked. The most recent BP measurement may be recalled by pressing the REVIEW button.

When in Automatic Mode, if the unit is unable to determine the systolic or diastolic value, the measurement will be automatically repeated once.

II. 1. A. MAX/MIN BLOOD PRESSURE RANGES

The maximum and minimum ranges of blood pressure are detailed below:

Measurement	Maximum	Minimum
Systolic Pressure	250 mmHg	60 mmHg
Diastolic Pressure	160 mmHg	30 mmHg

II. 1. B. BLOOD PRESSURE MANUAL MODE

In the Manual Mode, a single blood pressure determination is made only when the START button is pushed. The manual mode is the default mode of operation for blood pressure determinations.

A measurement cycle may be cancelled at any time by pressing the CANCEL button. This action immediately initiates a rapid cuff deflation.

The blood pressure measurement data will appear on the display immediately following the measurement. The display will blank after two minutes. If the display is blanked, pressing the REVIEW button on the front panel will recall the measurement. Up to 99 prior measurements are available for review or printing.

In Blood Pressure Manual Mode, the following alarm limits may be activated; SYSTOLIC HIGH LIMIT, SYSTOLIC LOW LIMIT, DIASTOLIC HIGH LIMIT, DIASTOLIC LOW LIMIT, PULSE RATE HIGH LIMIT and PULSE RATE LOW LIMIT. Blood pressure determinations which activate alarms are indicated by flashing displays and a repetitive audible tone. If an alarm limit is violated, subsequent blood presssure determinations may be made only after the alarm condition is reset by pressing any button on the Monitor's display.

II. 1. C. BLOOD PRESSURE AUTOMATIC MODE

The Automatic Blood Pressure Mode is entered by pressing the AUTO button. Pressing the AUTO button displays a choice of 11 cycle interval times as follows: "St" (STAT mode), 1 minute, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes and 90 minutes. These choices represent the time interval from the beginning of one cycle to the beginning of the next automatic cycle. STAT mode allows the monitor to take continuous blood pressure measurements for 15 minutes. In addition, the operator may choose to disable the Auto Mode by choosing "--" (two dashes).

Note: In the 1-minute automatic cycle mode, the Welch Allyn Vital Signs Monitor will automatically take blood pressure measurements in 1-minute intervals for up to 15 minutes.

A measurement cycle may be cancelled at any time by pressing the CANCEL button. This action immediately initiates a rapid cuff deflation.

The blood pressure measurement data will appear on the display immediately following the measurement and will remain displayed until the next measurement cycle is initiated.

In Blood Pressure Auto Mode, the following alarm limits may be activated; SYSTOLIC HIGH LIMIT, SYSTOLIC LOW LIMIT, DIASTOLIC HIGH LIMIT, DIASTOLIC LOW LIMIT, PULSE RATE HIGH LIMIT and PULSE RATE LOW LIMIT. Blood pressure determinations which activate alarms are indicated by flashing displays and a repetitive audible tone. Any alarm limit violation must be reset to continue automatically timed blood pressure determinations. The alarm may be reset by pressing any button on the Monitor's display.

II. 2. TEMPERATURE OPERATING MODES

Thermometry measurements are made with the integrated Welch Allyn SureTemp™ thermometer. Oral and rectal probes utilize single-use disposable probe covers which limit cross-contamination. Oral or rectal temperatures are taken using 'Normal' or 'Monitor' operating modes. Axillary temperatures may be taken using the oral probe in the Monitor operating mode.

In Normal Mode the thermometer's microprocessor "predicts" body temperature in about 4 seconds for oral temperatures and in about 15 seconds for rectal temperatures. The Monitor Mode displays the patient's actual temperature after 3 minutes and will continue to display an updated temperature as long as the probe remains in place.

Temperature readings may be displayed in Fahrenheit or Celsius scales.

II. 2. A. MAX/MIN TEMPERATURE RANGES

Readings	Normal Mode	Monitor Mode
Temperature	Max 108.0°F Max 42.2°C	Max 108.0°F Max 42.2°C
	Min 84.0°F Min 28.9°C	Min 84.0°F Min 28.9°C

II. 2. B. TEMPERATURE NORMAL MODE

In Normal Mode, the device will measure temperature at discrete intervals and then calculate the rate of change according to a proven algorithm. This allows the thermometer to predict the end point that the thermistor would reach if it were left in the mouth until it reached mouth temperature. This predictive feature allows the thermometer to arrive at an accurate oral temperature reading in approximately 4 seconds.

Normal mode is the default operating mode for temperature determinations.

Operator selectable patient alarm limits are not available in Temperature Normal Mode. However, temperatures which are outside of the operating range of the device will be noted on the temperature display.

II. 2. C. TEMPERATURE MONITOR MODE

Continuous Monitor Mode operation is normally used for longer term monitoring and when difficult situations prevent accurate temperatures from being taken in the normal mode. The probe must be in contact with tissue for at least three (3) minutes for accurate temperature measurement. Monitor mode temperatures may not be identical to predicted 'Normal' temperatures because of ambient temperature influence and other factors. The trend in temperature is the important standard to be observed when in the Monitor mode.

Operator selectable patient alarm limits are not available in temperature monitor mode. However, temperatures which are outside of the normal operating range of the device will be noted on the temperature display.

II. 3. SpO_2 OPERATING MODE

The Welch Allyn Vital Signs Monitor incorporates either the Nonin® or Nellcor Puritan Bennett™ pulse oximetry module which determines arterial oxyhemoglobin saturation (SpO_2%) by measuring the absorption of red and infrared light passed through the tissues. Changes in absorption caused by pulsation of blood in the vascular bed are used to determine arterial saturation and pulse rate.

Oxygen saturation percent is calculated with each pulse detected, and thus the monitor display is continually updated. The pulse signal bar graph is an indicator of the strength and quality of the detected pulses.

When SpO_2 is measured, the patient's pulse rate is also measured and displayed. A pulse rate measurement from the SpO_2 determination overrides a pulse rate measurement derived from a blood pressure measurement.

In SpO_2 monitoring mode, operator selectable alarm limits for low SpO_2 % may be activated. A condition which violates the SpO_2 low limit alarm is indicated by a flashing display and repetitive audible tone. Should a patient alarm condition for SpO_2 or pulse rate occur, the Monitor will indicate an alarm condition (flashing & beeping) while continuing to monitor and display the patient's current SpO_2%. The alarm will automatically reset when the patient's condition returns to within the preset alarm parameters.

Should a patient alarm condition for SpO_2 or pulse rate occur, the operator may invoke "Silence Mode" by pressing the SILENCE button. This will silence the audible tone (display will continue to flash), while the practitioner attends to the patient and the monitor. Silence mode resets automatically after 30 seconds, or when the patient's condition returns to within the preset alarm parameters.

Removal of the SpO_2 sensor from the patient will initiate an alarm, unless the SpO_2 and pulse rate alarms are turned off. To reset the sensor alarm, press any button on the Monitor's display.

SpO_2 is generally measured via pulses detected using a finger sensor. However, for certain situations SpO_2 may be measured at alternate sites including the earlobe, forehead and toes. Special sensors must be employed in these situations.

II. 3. A. MAX/MIN SpO_2 RANGES

The SpO_2 sensor is designed to detect oxygen saturation as follows.

	Maximum	Minimum
SpO_2	99%	40%

II. 3. B. SpO_2 MONITOR MODE

The SpO_2 monitor performs most accurately with the fingerclip sensor, which may be used on all fingers except the thumb. The finger clip sensor is recommended for spot checks or short term continuous monitoring.

The device determines arterial oxyhemoglobin saturation (SpO_2 %) by measuring the absorption of red and infrared light passed through the tissue. Oxygen saturation and pulse rate are displayed on the LED digital display. On each detected pulse, the pulse signal bar graph flashes. The intensity of this signal is a simple visual indicator of waveform signal strength, and can identify situations where the pulsatile nature of the tissue may not be adequate for an accurate SpO_2 reading. The update interval of the bar graph should correspond to the patient's pulse rate. This is an indication of the quality of the SpO_2 signal.

II. 4. PULSE RATE FEATURE

The Welch Allyn Vital Signs Monitor is capable of determining pulse rate as an adjunct to the blood pressure measurement and the SpO_2 measurement.

The pulse rate, in beats per minute, will be determined primarily from the SpO_2 measurement methodology. In the case where SpO_2 is not available, or is disabled, the pulse rate display will be driven by data from the blood pressure measurement method.

There are two operator selectable alarm limits for the pulse rate. They are PULSE RATE HIGH LIMIT and PULSE RATE LOW LIMIT. Pulse rates which activate alarm limits are indicated by a flashing display and a repetitive audible tone.

Should a pulse rate alarm occur when the pulse rate measurement is derived from the blood pressure measurement, no subsequent blood pressure or pulse rate measurements may be made until the alarm is reset. The alarm may be reset by pressing any button on the Monitor's display.

Should a pulse rate alarm occur when the pulse rate measurement is derived from the SpO_2 measurement, the monitor will indicate an alarm condition (flashing & beeping) while continuing to monitor and display the patient's current SpO_2% and pulse rate. The alarm will automatically reset when the patient's condition returns to within the preset alarm parameters.

Should a patient alarm condition for pulse rate occur during SpO_2 monitoring, the operator may invoke "Silence Mode" by pressing the SILENCE button. This will silence the audible tone (display will continue to flash), while the practitioner attends to the patient and Monitor. Silence mode resets automatically after 30 seconds, or when the patient's condition returns to within the preset alarm parameters. If an alarm limit is violated, subsequent determinations of any type may only be made after the alarm condition is reset.

II. 4. A. MAX/MIN PULSE RATE RANGES

The maximum and minimum pulse rate ranges are as follows:

	Maximum	**Minimum**
Pulse Rate	200 bpm	40 bpm

II. 5. PERFORMANCE SPECIFICATIONS

The performance specifications of the Welch Allyn Vital Signs Monitor are as follows:

CUFF PRESSURE RANGE
0 mmHg - 300mmHg

INITIAL CUFF INFLATION
120 mmHg, 140 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 240 mmHg or 280 mmHg depending on pressure preset level.

SYSTOLIC DETERMINATION
Maximum: 250 mmHg
Minimum: 60 mmHg

DIASTOLIC DETERMINATION
Maximum: 160 mmHg
Minimum: 30 mmHg

BLOOD PRESSURE ACCURACY
Blood pressure accuracy meets or exceeds SP10-1992 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: ± 5 mmHg mean error; 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.

BLOOD PRESSURE DETERMINATION TIME
20 seconds to 45 seconds typical, 165 seconds maximum.

PULSE RATE DETERMINATION
Maximum: 200 bpm
Minimum: 40 bpm

PULSE RATE ACCURACY

SpO_2 Module Heart Rate (Nonin®)	±3.0%
SpO_2 Module Heart Rate (Nellcor Puritan Bennett™)	±3 bpm
Blood Pressure Algorithm Heart Rate	±5.0%

OVERPRESSURE CUTOFF
295 mmHg to 330 mmHg

TEMPERATURE DETERMINATION

Normal Mode	Maximum	108.0°F (42.2°C)
	Minimum	84.0°F (28.9°C)
Monitor Mode	Maximum	108.0°F (42.2°C)
	Minimum	84.0°F (28.9°C)

TEMPERATURE ACCURACY
Temperature accuracy meets ASTM E112-86: "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature."

TEMPERATURE DETERMINATION TIME
Normal Mode: ORAL: 4 seconds typical, 15 seconds maximum
Monitor Mode: ORAL: 3 minutes

OXYGEN SATURATION RANGE (SpO_2%)
40-99% oxygen saturation

SpO_2 ACCURACY
Nonin® Pulse Oximeter Module
Saturation (%SpO_2 ± 1 Standard Deviation*)
70-99% ± 2 digits
< 70% unspecified

Nellcor Puritan Bennett™ Pulse Oximeter Module
Saturation (%SpO_2 ± 1 Standard Deviation*)
70-99% ± 3 digits
< 70% unspecified

* Standard Deviation is a statistical measure: up to 32% of the readings may fall outside these limits.

BATTERY CHARGING
To at least 90% capacity in 12 hours. Unit will operate and charge battery simultaneously when connected to power source.

A fully charged battery will support 200 "typical" blood pressure determinations taken at 3 minute intervals. Battery is 90-100% charged after 12 hours of charging. The battery automatically charges when the monitor is powered through the AC power transformer. The battery will charge faster when the instrument is not in operation.

II. 6. A. TECHNICAL SPECIFICATIONS: MECHANICAL SPECIFICATIONS

DIMENSIONS

Height	6.5 inches	(16.5cm)
Length	8.6 inches	(21.8cm)
Depth	5.0 inches	(12.7cm)

WEIGHT
Approximately 6 pounds (2.8Kg)

COLOR
Oral Temperature Probe - Blue
Rectal Temperature Probe - Red

MOUNTING

Self-Supporting on rubber feet
IV Pole Mountable
Custom Mobile Stand
Wall Mountable
Attaches to Bed Rail

PORTABILITY

- May be hand carried when held by the recessed handle.
- When attached to an IV pole, or mounted on its custom mobile stand, the monitor and accessories can be wheeled from patient to patient.
- When attached to the bed rail may be transported with the patient within the hospital environment.

OPERATOR INSTRUCTIONS/ALARM INTERPRETATION

Comprehensive Operator Manual available. Quick reference operator instructions and alarm interpretation are located on side panel labels.

II. 6. B. ELECTRICAL SPECIFICATIONS

POWER REQUIREMENTS

Patient-Rated isolation transformer is connected to AC mains power source:

North American Version: 120VAC, 60 Hz.

International Versions: 220-240VAC, 50-60Hz.

BATTERY

Lead acid, with external recharge capability.

II. 6. C. ENVIRONMENTAL SPECIFICATIONS

OPERATING TEMPERATURE

+10°C to +40°C
+50°F to +104°F
Exception: Thermometry module will not maintain its performance characteristics below 60°F (16°C).

STORAGE TEMPERATURE

-20°C to +50°C
-4°F to +122°F

RELATIVE HUMIDITY

15 to 90% (non-condensing)

OPERATING ALTITUDE

-170m to +1700m
-557ft. to +5577ft.

SECTION III
SYSTEM INSTALLATION

1. Unpacking Checklist
2. Controls, Indicators and Connections
3. Set Up Procedure
    a. Blood Pressure Hose & Cuff Connections
    b. Temperature Probe Connection
    c. SpO_2 Sensor Connection
    d. AC Power Connection
    e. Charging the Battery
    f. Setting Up the Printer
    g. Changing the Time and Date Setting
4. Safety Warnings and Cautions

III. 1. UNPACKING CHECKLIST

After you have unpacked the Welch Allyn Vital Signs Monitor and the components, identify each item with the checklist that follows and inspect for missing items. Retain the shipping materials in the event of shipping damage or for return, if necessary, to Welch Allyn/Tycos for repair or warranty service.

All Welch Allyn Vital Signs Monitors include the following components (A-G):

A. **Welch Allyn Vital Signs Monitor**
This device is a portable, light weight device designed to automatically measure and display blood pressure and pulse rate. Options available include pulse oximetry, temperature and integrated printer.

B. **Operator Manual** (This manual)
To achieve satisfactory results, the operator should read this manual thoroughly before attempting to use the monitor. Save this manual for helpful product reference.

C. **Instrument Warranty Card**
Fill this out today and return to Welch Allyn. This card validates your warranty.

D. Adult Size Cuff Assembly
Includes cuff, bladder and pneumatic tubing with connector. Other size cuff assemblies are available separately.

E. Coiled Pressure Hose
With connector, connects a variety of blood pressure cuffs to the monitor.

F. Power Transformer and Cord Assembly
Operates the monitor and charges the internal battery.

G. Cuff Clip
Attaches to the rear of the monitor to hold the blood pressure cuff. Not used if mobile stand, pole mount or wall mount accessories are purchased.

Certain Welch Allyn Vital Signs Monitors will include the following items, based on the options purchased:

PRINTER OPTION

H. Box of Printer Paper
Six (6) rolls of thermal printer paper. One additional roll will be pre-loaded into the printer.

PULSE OXIMETRY (SpO_2) OPTION

I. Finger Clip SpO_2 Sensor and Cord
Other sensors are available separately.

TEMPERATURE OPTION

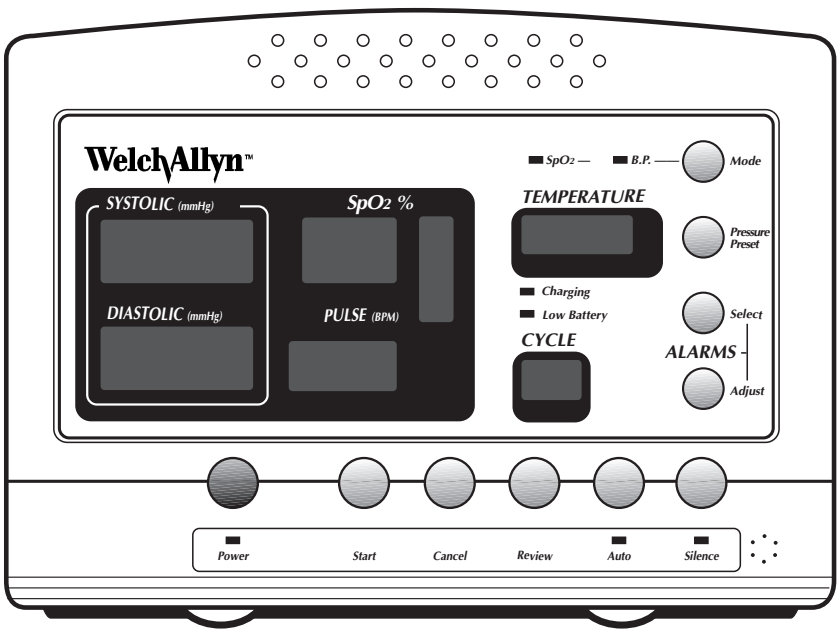
J. Oral Temperature Probe
The blue oral probe is used for both oral and axillary temperature determinations. A red rectal probe is available separately.

K. Temperature Probe Covers
One box of 25 single use, disposable probe covers for both oral and rectal temperature determinations.

Note: Report any signs of shipping damage to the carrier. If an item is missing or damaged, contact the Welch Allyn Service Center near you. See section VI of this manual for more information

III. B. CONTROLS, INDICATORS AND CONNECTIONS

Note: In this section, all drawing and text are representative of the Welch Allyn Vital Signs Monitor with all available options (i.e. Blood Pressure plus Pulse Oximetry (SpO_2), Temperature and Printer). Your Monitor may not include all functions, depending on the options purchased.



FRONT PANEL

FRONT PANEL FUNCTIONS:

A. POWER Button & Indicator Light
This on/off button controls the power to the Monitor. The indicator light will glow when the unit is on. Battery power will be used unless the Monitor is powered through the AC power transformer.

B. START Button
Pressing this button initiates an on-demand blood pressure cycle.

C. CANCEL Button
If a blood pressure cycle is in progress, pressing this button aborts the cycle and immediately releases the cuff pressure. In "STAT" automatic blood pressure mode, pressing the cancel button aborts the cycle in process, and cancels the "STAT" mode as well.

When pressed for 3 seconds, the cancel button erases all stored data in the Welch Allyn Vital Signs Monitor.

D. REVIEW Button
Pressing this button will display the most current set of stored data including BP & pulse rate and/or SpO_2 and/or temperature. Subsequent presses will display the next most recent data sets.

E. AUTO Button & Indicator
Pressing this button allows the operator to scroll through the automatic blood pressure interval options. Time intervals are displayed in minutes on the CYCLE display (see "Q" below). Choosing any time interval except "--" will cause the Auto indicator light to glow, and blood pressure determinations to be made according to the displayed time interval.

F. SILENCE Button & Indicator
During SpO_2 monitoring, should an SpO_2 or Pulse Rate alarm condition occur, pressing the Silence button invokes 'Silence Mode'. This will silence the audible tone (display will continue to flash), while the practitioner attends to the patient and Monitor. Silence mode resets automatically after 30 seconds, or when the patient's condition returns to within the preset alarm parameters. In Silence Mode, the silence indicator light will glow.

G. ALARMS SELECT Button
Pressing this button allows the operator to select a specific parameter for which an alarm threshold will be set. The HIGH ("HI") or LOW ("LO") indicator will show in the CYCLE display, and the current value will appear in the respective display.

H. ALARMS ADJUST Button
This button will increment the currently displayed alarm threshold.

The adjust button has additional functionality. See section IV.19.

I. PRESSURE PRESET Button
Pressing this button allows the operator to choose the target inflation pressure for manual blood pressure measurements. The target inflation pressure will be shown on the systolic display.

J. MODE Button and B.P., SpO_2 Indicators
This button activates the BP and SpO_2 modes independently. Pressing the mode button will allow the operator to choose BP only, BP plus SpO_2 and SpO_2 only.

When a particular mode is chosen the indicator light for that mode will glow.

K. SYSTOLIC DISPLAY
This red LED display shows the systolic blood pressure.

Additionally, this display can show systolic alarm limits, and target inflation pressure (see G, H, and I above).

L. DIASTOLIC DISPLAY
This red LED display shows the diastolic blood pressure

Additionally, this display can show diastolic alarm limits (see G, and H above).

M. SpO_2 DISPLAY
This red LED display shows the percent saturation of arterial hemoglobin (SpO_2%).
Additionally, this display can show SpO_2 low saturation alarm limits (see G, and H above).

N. PULSE SIGNAL BAR GRAPH
This bar graph gives a visual indication of the strength and quality of the pulses detected by the SpO_2 sensor.

O. PULSE DISPLAY
This yellow LED display shows the pulse rate.
Additionally, this display can show pulse rate alarm limits (see G and H above).

P. TEMPERATURE DISPLAY
The red LED display shows the temperature in degrees Fahrenheit or Celsius. The temperature scale (°F or °C) will be shown by a green indicator. Also, temperature monitor mode is indicated by a green indicator.

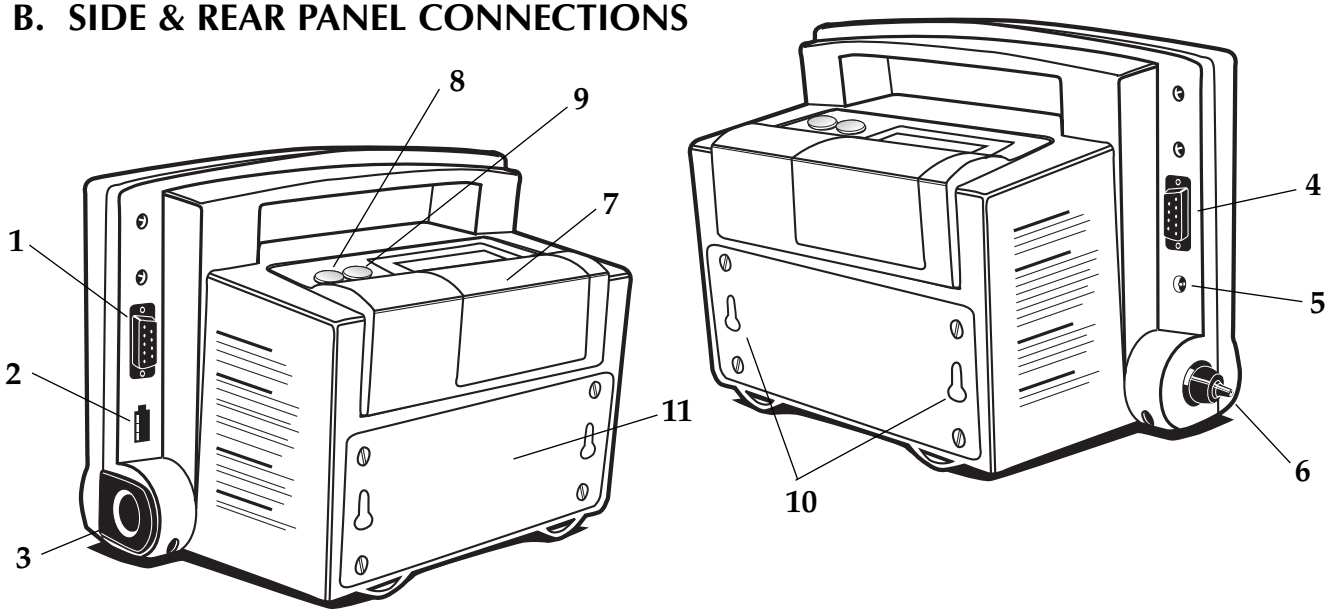
Q. CYCLE DISPLAY
This red LED display shows the time (in minutes) between automatically initiated blood pressure measurements, or "St" for STAT mode (continuous blood pressure measurements for up to 15 minutes).
Additionally, this display identifies the high and low alarm limits for the various parameters, during alarm select mode, and the cycle number during review mode.

R. CHARGING INDICATOR
This flashing yellow indicator will signify that the internal battery is being charged when the Monitor is powered through the AC power transformer. When the Monitor is fully charged, the flashing will be replaced with a solid yellow indicator light.

S. LOW BATTERY INDICATOR
This yellow indicator light will remain on continuously as a visual indicator when the battery charge is weak. The indicator will flash as a visual indicator that the battery charge is critically low.

T. MEMORY INDICATOR
This green indicator will flash when the unit has reached its maximum capacity of 99 data sets in storage. Also, it will remain on continuously when the operator is reviewing stored data sets.

B. SIDE & REAR PANEL CONNECTIONS



1. **SpO_2 Sensor Connection**
   Nine pin connector for the SpO_2 sensor.

2. **Temperature Probe Connector**
   Connector for either oral (blue) or rectal (red) probe.

3. **Temperature Probe Holder**
   Active temperature probe is inserted here when not in use. Removing and replacing the probe turns the temperature on and off, respectively.

4. **RS232 Data Interface Connector**
   Port for the connection of a cable to an external computer or network.

5. **Transformer Power Connector**
   AC power transformer connector.

6. **Pressure Hose Connector**
   Connector for black, coiled pressure hose.

7. **Printer**
   Compartment and paper feed area for integrated thermal printer.

8. **Print Button**
   Pressing this button initiates a print operation.

9. **Printer Feed Button**
   Pressing this button advances the paper in the printer.

10. Mounting Keyholes
Mounting accessories are attached via these keyholes.

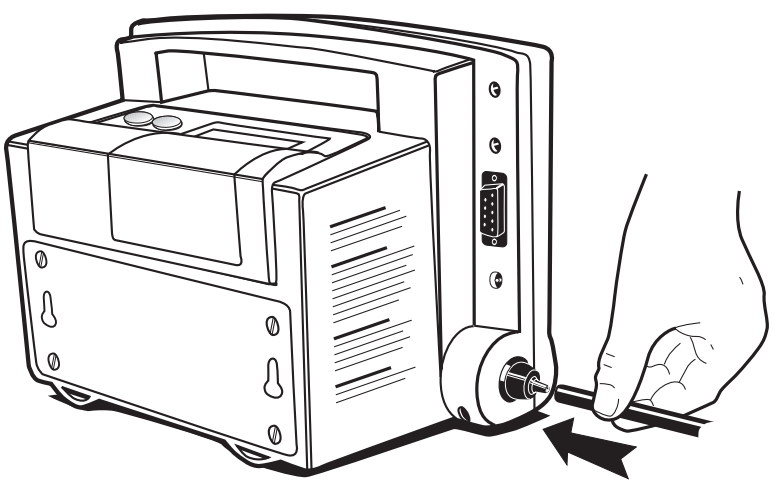
11. Battery Compartment
Contains the internal battery. Removal of 4 screws allows changing battery without affecting other internal parts.

III. 3. A. SET-UP PROCEDURE: BLOOD PRESSURE HOSE & CUFF CONNECTIONS

Identify and have available each of the following items:
-The Welch Allyn Vital Signs Monitor
-Cuff and bladder assembly
-Black coiled pressure hose

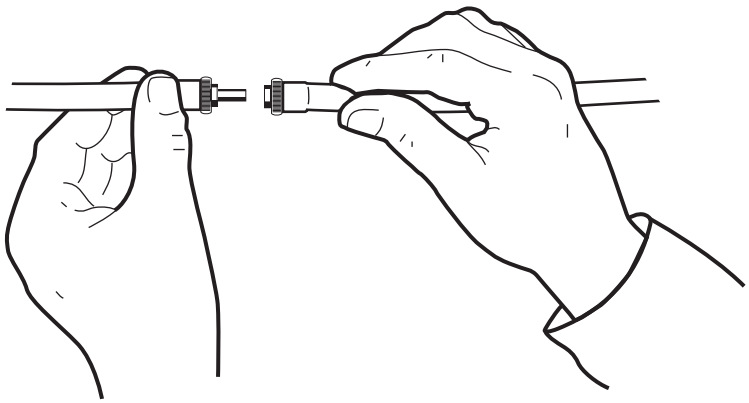
Using the illustrations below for reference, perform the following set-up procedures:

1. Inspect the black coiled pressure hose and note that one end has a connector fitting and the other end does not. Attach the end <u>without</u> the connector to the pressure hose connector on the monitor by fitting the pressure hose on to the connector as shown. Be sure that the pressure hose is completely inserted over the connector and into the recess, and that the fit is snug.



Attaching pressure hose to connector on monitor

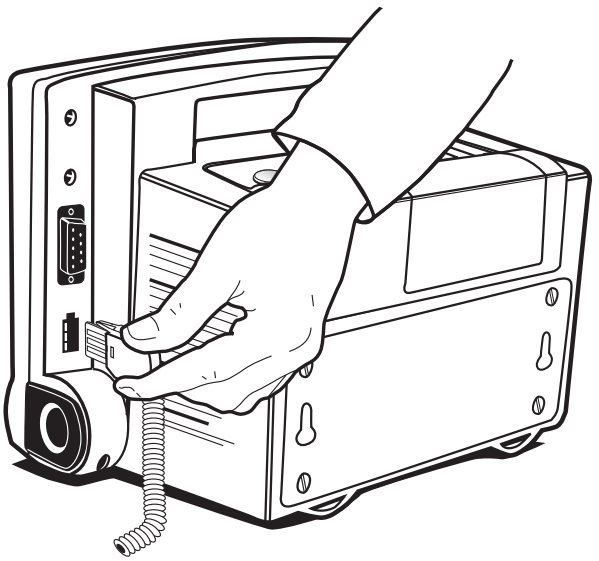
2. Join the other end of the black coiled pressure hose to the pneumatic tubing which is attached to the cuff. Twist the black plastic connectors together until finger-tight. DO NOT OVER TIGHTEN.



III. 3. B. SET-UP PROCEDURE: TEMPERATURE PROBE CONNECTION

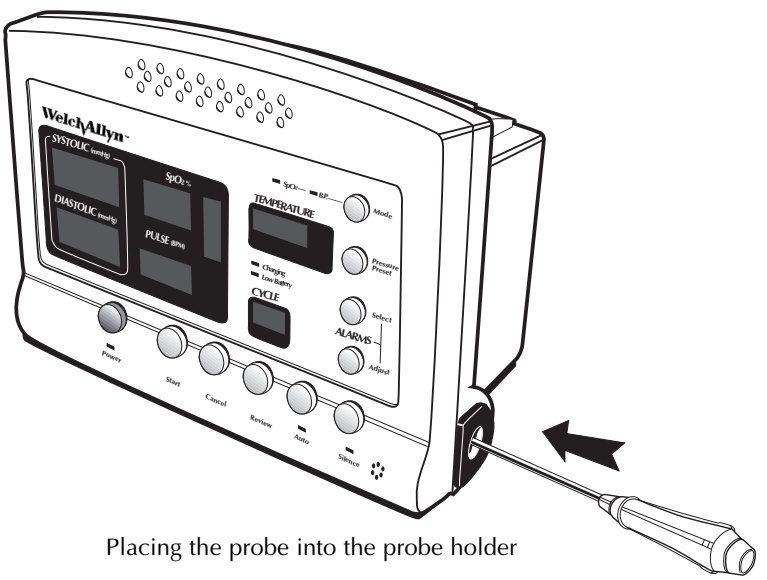
The Welch Allyn Vital Signs Monitor is available with two probes; one for oral temperatures (blue), and one for rectal temperatures (red). The rectal probe is an accessory item and must be ordered separately.

To install the temperature probe, press down on the tab on top of the connector and insert the connector into the temperature probe connector port on the side of the Monitor until the connector clicks into place. The temperature connector port on the Monitor is clearly labeled "TEMP." The probe connector can only be inserted one way, with the tab on top. The temperature probe should be inserted into the probe holder on the side of the Monitor.



Inserting the probe connector into the Monitor port

Should removal of the temperature probe be necessary, press down on the connector tab and slide the connector out.



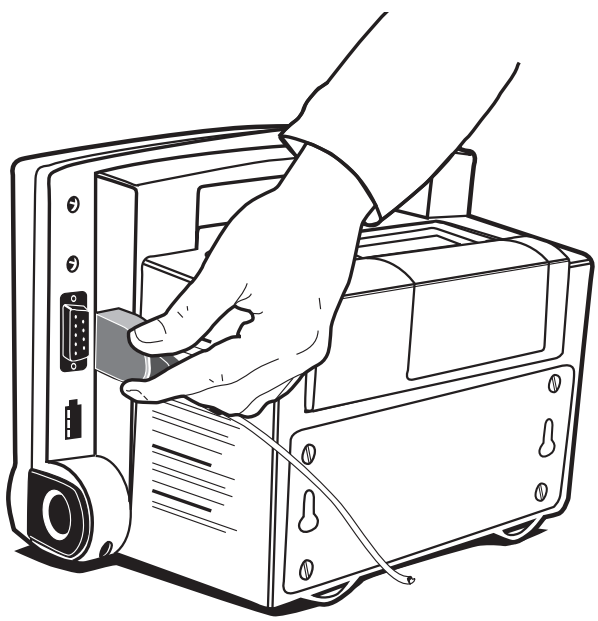
Placing the probe into the probe holder

III. 3. C. SET-UP PROCEDURE: SpO_2 SENSOR CONNECTION

The Welch Allyn Vital Signs Monitor is available with a wide variety of SpO_2 sensors. The reusable finger clip sensor is shipped with the Monitor. All other sensors may be ordered separately as accessory items.

For Welch Allyn Vital Signs Monitor with the Nonin® Pulse Oximetry Option:
To install the Nonin SpO_2 sensor, insert the connector end of the sensor into the SpO_2 connector port on the side of the Monitor as shown. The SpO_2 connector port on the Monitor is clearly labeled "SpO_2." The sensor connector can only be inserted one way, matching the shape and pin configuration of the connector to the port. Push the connector in until it is fully seated on the port. Note: only Nonin® SpO_2 sensors and accessories may be used with this configuration of the Welch Allyn Vital Signs Monitor.

For Welch Allyn Vital Signs Monitor with the Nellcor Puritan Bennett™ Pulse Oximetry Option:
Attach the Nellcor Puritan Bennett SpO_2 sensor to the pulse oximetry extension cable. Then insert the connector end of the extension cable into the SpO_2 connector port on the side of the Monitor as shown. The SpO_2 connector port on the Monitor is clearly labeled "SpO_2". The extension cable can only be inserted one way; matching the shape and pin configuration of the connector to the port. Push the connector in until it is fully seated on the port. Note: Only Nellcor Puritan Bennett™ SpO_2 sensors and accessories may be used with this configuration of the Welch Allyn Vital Signs Monitor.

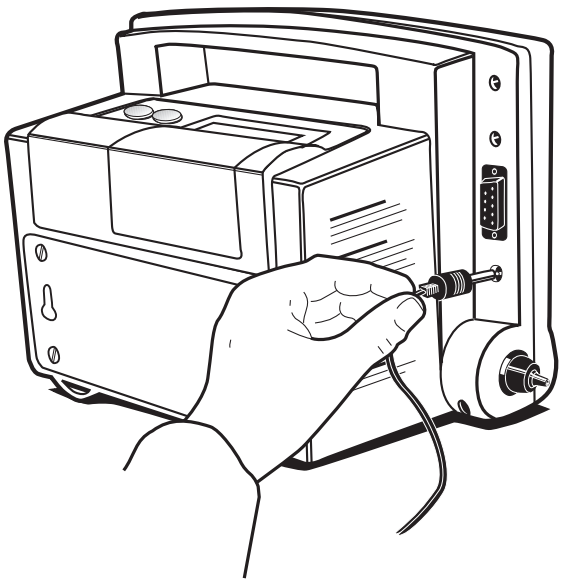


Inserting the sensor connector into the Monitor port.

III. 3. D. SET-UP PROCEDURE: AC POWER CONNECTION

The Welch Allyn Vital Signs Monitor may be powered by either AC power or battery power after the battery has been charged.

To install the AC power transformer, insert the round transformer connector into the power port on the side of the Monitor as shown. Insert the connector into the port until it is fully seated. If the desktop version of transformer is used, insert the line cord into the line connector on the transformer.



Inserting the AC power transformer connector into the Monitor port

To power the Welch Allyn Vital Signs Monitor, plug the AC power transformer into the AC mains power source.

III. 3. E. SET-UP PROCEDURE: CHARGING THE BATTERY

The Welch Allyn Vital Signs Monitor may be powered by either AC power or battery power after the battery has been charged.

UPON INITIALLY RECEIVING THE MONITOR, CHARGE THE BATTERY FOR SIX-TEEN (16) HOURS OR UNTIL THE CHARGING INDICATOR LIGHT NO LONGER FLASHES. The battery is charged by attaching the AC power transformer to the Monitor, and plugging the AC power transformer into the AC mains power source.

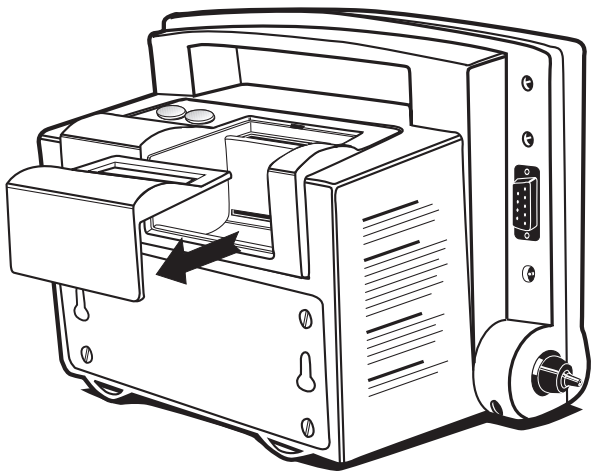
While charging, the charging indicator will flash a yellow light. When the Monitor is fully charged the flashing light will be replaced with a solid yellow indicator light.

III. 3. F. SET-UP PROCEDURE: SETTING UP THE PRINTER

A fully integrated thermal printer is available as an option to the Welch Allyn Vital Signs Monitor.

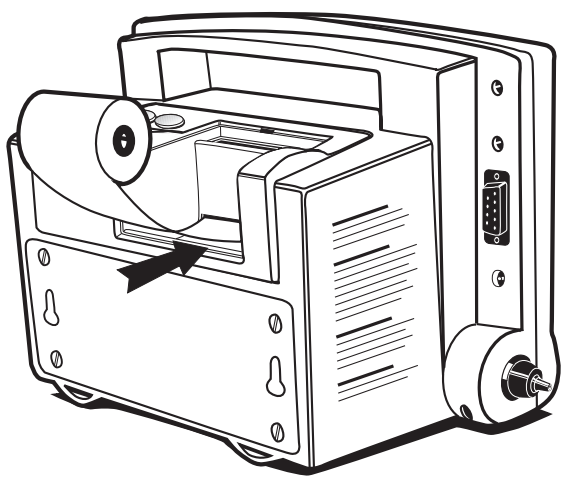
To load paper into the printer follow these steps:

1. Grasp the printer cover as shown, and slide the cover off of the Monitor by sliding the cover towards you.



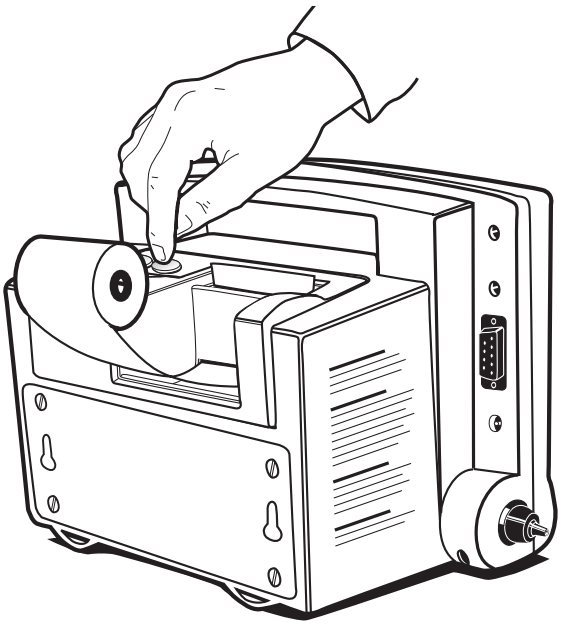
Sliding off the printer cover

2. Holding a new roll of paper as shown, feed approximately 1 inch of paper into the slot at the bottom of the paper holder. Release the paper roll so that it sits in the bottom of the paper holder.



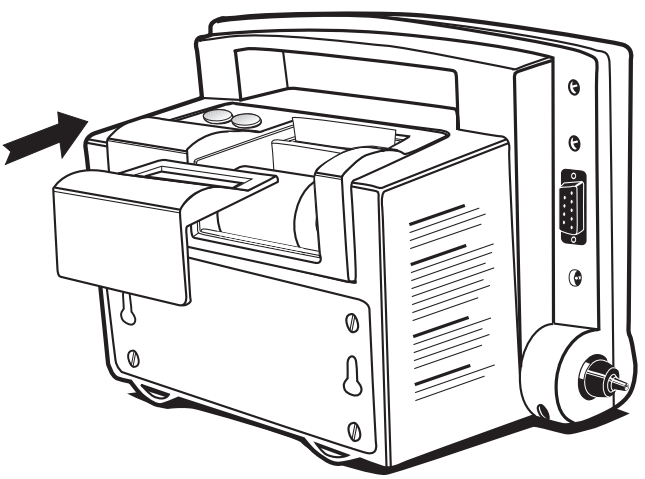
Feeding the paper into the slot

3. Press the paper "FEED" button to advance the paper 3 to 4 inches above the top paper slot.



Advancing the paper

4. Thread the paper through the paper slot on the printer cover. Slide the cover on to the Monitor and press down until it clicks into place as shown. The excess paper may be torn off if desired.



Replacing the printer cover

Note: The operator will notice a red stripe along the edge of the printer paper when the paper roll is almost at the end. Replace the printer paper with a new roll when the red stripe is observed.

III. 3. G. SET-UP PROCEDURE: CHANGING THE TIME / DATE SET

1 Initiate the Monitor's internal configuration settings menu by powering up the unit while the START button is depressed. Hold the START button down until all the LED display segments go off. The first message displayed is the revision level of the internal software. This will be displayed in the systolic and diastolic displays.

2 Press the review button four (4) times to advance to the Date Set Screen. The year, month and day will appear in the systolic, diastolic and heart rate displays respectively.

3 Use the SELECT button to select the date item to be changed. When selected, the date item will flash.

4 Use the ADJUST button to change the selected date item.

5 After making all the desired date changes, press the REVIEW button the save the changes and advance to the Time Set Screen.

6 When in the Time Set Screen the hour (in 24 hour format) and minutes will appear in the systolic and diastolic displays respectively. Use the SELECT and ADJUST buttons to set the time (in the same manner as described above).

7 When the time is set as desired, press the REVIEW button to save the time and advance to the next screen.

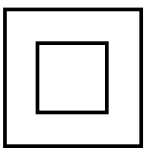
8 Press the POWER button to turn the Monitor off.

III. 4 SAFETY WARNINGS & CAUTIONS

All operating personnel should be familiarized with the general safety information in this summary. Specific warnings and cautions will also be found throughout the operator's manual. Such specific warnings and cautions may not appear here in this summary.

Conforms to IEC 601-1
UL 2601
C22.2 No 601-1

Approved to Australia AS 3200.1, Appendix 2



Class II Equipment

Type BF Equipment, Defibrillator Proof

Attention, Consult Accompanying Document

GENERAL WARNINGS

- The Welch Allyn Vital Signs Monitor is designed for use by medical clinicians. Although this manual may illustrate medical monitoring techniques, this system should only be used by a trained clinician who knows how to take and interpret a patient's vital signs.
- The information in this operator's manual is a comprehensive guide to the operation of the Welch Allyn Vital Signs Monitor. To achieve satisfactory results the operator should read the manual thoroughly before attempting to use the Monitor.
- To insure patient safety, use only accessories and supplies (i.e. cuffs, hoses, temperature probes, SpO_2 sensors etc.) recommended or supplied by Welch Allyn for the Welch Allyn Vital Signs Monitor.
- Do not operate the Welch Allyn Vital Signs Monitor in the presence of flammable anesthetics or other explosive atmosphere. An explosion may result.
- It is the operator’s responsibility to set alarm limits as appropriate for each individual patient.

- Any Monitor which has been dropped or damaged should be checked by qualified service personnel to insure proper operation prior to use.
- Cords should periodically be checked for fraying or other damage, and replaced as necessary.
- There are no user serviceable parts inside the Monitor other than paper replacement and battery replacement.
- This Monitor is not designed for use with neonates, infants or children under the age of 3 years.
- This Monitor should not be used on patients who are linked to heart/lung machines.
- This Monitor will not operate effectively on patients who are experiencing convulsions or tremors.

BLOOD PRESSURE WARNINGS

- Blood pressure measurements may be inaccurate if cuffs and/or hoses are used other than those provided for the Welch Allyn Vital Signs Monitor by Welch Allyn.
- Blood pressure measurements may not be accurate for patients experiencing moderate to severe arrhythmias.
- When monitoring over an extended period of time, or at frequent intervals, it is recommended to check the cuff site and cuffed extremity regularly for possible ischemia, purpura and/or neuropathy.

SpO_2 WARNINGS

- The operation of the SpO_2 sensor in MRI environments is specifically not recommended.
- Use only SpO_2 sensors and accessories which are compatible with the SpO2 configuration purchased. Welch Allyn Vital Signs Monitor with the Nonin® pulse oximetry option may only be used with Nonin® brand SpO_2 sensors and accessories. Welch Allyn Vital Signs Monitor with Nellcor Puritan Bennett™ pulse oximetry option may only be used with Nellcor Puritan Bennett™ brand sensors and accessories.

TEMPERATURE WARNINGS

- Single-use, disposable probe covers, available from Welch Allyn will limit patient cross-contamination. The use of any other probe cover or the failure to use a probe cover may produce temperature errors and is specifically not indicated.
- Oral probes (blue) are to be used for taking oral and axillary temperatures only. Rectal probes (red) are to be used for taking rectal temperatures only. The use of the wrong probe may produce temperature errors.

GENERAL CAUTIONS

- If the accuracy of any measurement is in question, check the patient's vital sign(s) by an alternate method and then check the Monitor for proper functioning.

- Insure the Monitor is placed on a secure surface or use one of the optional mounting accessories. Do not place fluids on the Monitor.

BLOOD PRESSURE CAUTIONS

- Extremity and cuff motion should be minimized during blood pressure determinations.

- If the blood pressure cuff is not at heart level, the difference in reading due to the hydrostatic effect should be noted. The value of 1.80 mmHg must be added to the displayed reading for every inch (2.5cm) above heart level. The value of 1.80 mmHg must be subtracted from the displayed reading for every inch (2.5cm) below heart level.

- Proper blood pressure cuff size and placement is essential to the accuracy of the BP determination. See Section IV.7 for cuff sizing information.

SpO_2 CAUTIONS

- The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobins such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.

- Some intravascular dyes, depending on the concentration, may affect the accuracy of the SpO_2 measurement.

- Some sensors may not be appropriate for a particular patient. If at least 10 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type until this condition is achieved.

TEMPERATURE CAUTIONS

- Do not allow the tip of the temperature probe to come into contact with a heat source (i.e. hands or fingers) prior to taking a temperature measurement. If this occurs discard the probe cover and start the temperature determination process again.

- Axillary temperatures should only be taken in monitor mode. Axillary temperatures taken in the normal 'predictive' mode may not be accurate.

SECTION IV
OPERATING PROCEDURES

1. Power On/System Check Procedure
2. Choosing Operating Modes
3. Setting the Programmable Alarms
    a. Blood Pressure - High Systolic Limit
    b. Blood Pressure - Low Systolic Limit
    c. Blood Pressure - High Diastolic Limit
    d. Blood Pressure - Low Diastolic Limit
    e. Pulse Rate - High Limit
    f. Pulse Rate - Low Limit
    g. SpO_2 - Low Limit
4. Non-Programmable Alarms: Temperature
5. Alarm Indications and Interpretation
6. Setting the Inflation Pressure Preset Level
7. Blood Pressure Cuff Selection Criteria
8. Positioning the Blood Pressure Cuff
9. Manual Mode Blood Pressure
10. Automatic Mode Blood Pressure
11. Reviewing Information from Prior Cycles
12. Selecting the Temperature Scale
13. Selecting Temperature Operation Mode
14. Taking Oral Temperature
15. Taking Rectal Temperature
16. SpO_2 Operation Mode
    a. Using the Finger Clip Sensor
    b. Other Sensors
    c. Taking an SpO_2 Measurement
17. Printer Operation
    a. Printing Options: Batch Print or Streaming Print Mode
18. Using the RS232 Computer Interface
19. Mean Arterial Pressure (MAP)/Data Send Mode/Data Stream Mode

IV.1. POWER ON/OFF AND SYSTEM CHECK PROCEDURE

Each time the Welch Allyn Vital Signs Monitor is turned on, the unit performs an internal self-diagnostic check.

To turn the unit on, press the POWER button.
Upon power up, note that all of the LED segments in each display turn on briefly. An audible tone should also sound. If the internal self-check is successful, the displays will assume their normal functions and the monitor is ready for operation. If the self-check fails, an error code will be shown in the displays.

To turn the unit off, press POWER button.
Note that turning the unit off will erase all stored blood pressure, temperature, SpO_2 and pulse rate data.

IV.2. CHOOSING OPERATING MODES

For all Welch Allyn Vital Signs Monitors which are configured with blood pressure and SpO_2 capability, the operator may choose to make either parameter non-functional.

On power up, the default setting is for both blood pressure and SpO_2 capabilities to be functional. This is indicated by lit green SpO_2 and B.P. indicators next to the MODE button.

To disable the blood pressure function, press the MODE button once. Note that the SpO_2 indicator is ON and the B.P. indicator is OFF.

To disable the SpO_2 function, press the MODE button again. Note that the B.P. indicator is ON and the SpO_2 indicator is OFF.

To resume both functions, press the MODE button once again. Note that the indicators for both SpO_2 and B.P. are on. This indicates that both functions are operational.

It is not possible to disable both the SpO_2 and the B.P. functions simultaneously.

IV. 3. SETTING THE PROGRAMMABLE ALARMS

The Welch Allyn Vital Signs Monitor has the ability to generate a visual and audible alarm when certain patient conditions are detected by the monitor. The following chart outlines the conditions, ranges, programming intervals and default values for the alarm function.

Warning: It is the operator's responsibility to set alarm limits as appropriate for each individual patient.

Programmable Alarm	Alarm Ranges	Programmable Intervals	Factory Default Values*
BP - High Systolic	245 - 65 mmHg	5 mmHg	240 mmHg
BP - Low Systolic	245 - 65 mmHg	5 mmHg	"---" (off)
BP - High Diastolic	35 - 155 mmHg	5 mmHg	130 mmHg
BP - Low Diastolic	35 - 155 mmHg	5 mmHg	"---" (off)
Pulse Rate - High	45 - 195 bpm	5 bpm	195 bpm
Pulse Rate - Low	45 - 195 bpm	5 bpm	45 bpm
SpO_2 - Low	98 - 70%O_2	1%O_2	"--" (off)

Note: Temperature default alarms are 108°F, 42.2°C (high) and 84.0°F, 28.9°C (low). The temperature alarms are not programmable, they indicate that the patient's temperature has exceeded the functional range of the thermometer.

*The unit will default to these factory settings only until the operator selects a different alarm limit. When a new alarm limit is selected, the Monitor will retain this new limit setting in memory, even if the Monitor is turned off.

Alarm limits may be reviewed or changed by using the ALARMS SELECT and ALARMS ADJUST buttons, and viewing the CYCLE display and the display of the parameters being changed.

IV. 3. A. SETTING THE PROGRAMMABLE ALARMS: BLOOD PRESSURE - HIGH SYSTOLIC LIMIT

Press the ALARMS SELECT button until the SYSTOLIC display is illuminated, and the CYCLE display shows "HI." This indicates the high systolic alarm setting.

The systolic display will show the current alarm limit for high systolic blood pressure in mmHg or three dashes ("---") if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 5 mmHg intervals. The operator may choose the high systolic blood pressure limit within the range of 245mmHg through the current low systolic alarm limit. The alarm may be turned off by choosing "---."

When the desired alarm limit is displayed, pressing ALARMS SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 3. B. SETTING THE PROGRAMMABLE ALARMS: BLOOD PRESSURE - LOW SYSTOLIC LIMIT

Press the ALARMS SELECT button until the SYSTOLIC display is illuminated, and the CYCLE display shows "LO." This indicates the low systolic alarm setting.

The Systolic display will show the current alarm limit for low systolic blood pressure in mmHg, or "---" if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 5 mmHg intervals. The operator may choose the low systolic blood pressure limit within the range of the current high systolic alarm limit through 65mmHg. The alarm may be turned off by choosing "---."

When the desired alarm limit is displayed, pressing ALARMS SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 3. C. SETTING THE PROGRAMMABLE ALARMS: BLOOD PRESSURE - HIGH DIASTOLIC LIMIT

Press the ALARMS SELECT button until the DIASTOLIC display is illuminated, and the CYCLE display shows "HI." This indicates the high diastolic alarm setting.

The diastolic display will show the current alarm limit for high diastolic blood pressure in mmHg, or "---" if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 5 mmHg intervals. The operator may choose the high diastolic blood pressure limit within the range of the current low diastolic limit through 155mmHg. The alarm may be turned off my choosing "---."

When the desired alarm limit is displayed, pressing ALARM SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 3. D. SETTING THE PROGRAMMABLE ALARMS: BLOOD PRESSURE - LOW DIASTOLIC LIMIT

Press the ALARMS SELECT button until the DIASTOLIC display is illuminated, and the CYCLE display shows "LO." This indicates the low diastolic alarm setting.

The diastolic display will show the current alarm limit for low diastolic blood pressure in mmHg, or "---" if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 5 mmHg intervals. The operator may choose the low diastolic blood pressure limit within the range of 35mmHg through the current high diastolic limit. The alarm may be turned off by choosing "---."

When the desired alarm limit is displayed, pressing ALARMS SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 3. E. SETTING THE PROGRAMMABLE ALARMS: PULSE RATE - HIGH LIMIT

Press the ALARMS SELECT button until the PULSE display is illuminated, and the CYCLE display shows "HI." This indicates the high pulse rate alarm setting.

The pulse display will show the current alarm limit for high pulse rate in bpm, or "---" if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 5 bpm intervals. The operator may choose the high pulse rate limit within the range of the current low pulse rate limit through 195bpm. The alarm may be turned off by choosing "---."

When the desired alarm limit is displayed, pressing ALARM SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 3. F. SETTING THE PROGRAMMABLE ALARMS: PULSE RATE - LOW LIMIT

Press the ALARMS SELECT button until the PULSE display is illuminated, and the CYCLE display shows "LO." This indicates the low pulse rate alarm setting.

The pulse display will show the current alarm limit for low pulse rate in bpm, or "---" if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 5 bpm intervals. The operator may choose the low pulse rate limit within the range of 45bpm through the current high pulse rate alarm limit. The alarm may be turned off by choosing "---."

When the desired alarm limit is displayed, pressing ALARMS SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 3. G. SETTING THE PROGRAMMABLE ALARMS: SpO_2 - LOW LIMIT

Press the ALARMS SELECT button until the SpO_2 display is illuminated, and the CYCLE display shows "LO." This indicates the low SpO_2 alarm setting.

The SpO_2 display will show the current alarm limit for the SpO_2% or "--" if the alarm is turned off. Pressing ALARMS ADJUST cycles through the options in 1% intervals. The operator may choose the low SpO_2% limit within the range of 98-70%, or the alarm may be turned off by choosing "--."

When the desired alarm limit is displayed, pressing ALARMS SELECT again saves the displayed alarm limit and changes the alarm parameter. Alternatively, pressing no buttons for approximately 10 seconds will cause the displayed value to be set as the alarm limit, and the Monitor will automatically revert to the current operating mode.

IV. 4 TEMPERATURE OPERATING RANGE INDICATORS

The high and low operating ranges of the temperature module are as follows:

HIGH OPERATING RANGE:	108.0°F	42.2°C
LOW OPERATING RANGE:	84.0°F	28.9°C

IMPORTANT: No audible tone will indicate that the temperature is outside of the operating range of the Monitor. This is a visual indicator only.

Temperatures which are outside of the operating range of the Monitor will cause the following to be displayed. Note the symbol shown in the tenths position of the display.

CONDITION	TEMPERATURE	DISPLAY
Temperature is outside of high operating range of the Monitor.	Fahrenheit	108 ⊓
	Celcius	42 ⊓
Temperature is outside of low operating range of the Monitor.	Fahrenheit	84 ⊔
	Celcius	28 ⊔

IV. 5. ALARM INDICATIONS AND INTERPRETATION

Patient alarms will be activated when the patient's systolic pressure, diastolic pressure, pulse rate or SpO_2% exceed the alarm limits programmed by the operator. Patient alarm conditions are visually indicated by flashing LED displays for the parameter in question, accompanied by a repetitive audible alarm tone.

The Welch Allyn Vital Signs Monitor handles patient alarms in the following manner:

NOTE: Pulse rate measurements from the SpO_2 determination *override* pulse rate measurements from the blood pressure determination.

DURING BLOOD PRESSURE MEASUREMENT:
Should a blood pressure or pulse rate patient alarm condition occur, no additional measurements may be initiated until the alarm is reset. Check the patient condition first, and then reset the patient alarm by pressing ANY BUTTON on the Monitor's display. Measurements may now be resumed.

DURING SpO_2 MEASUREMENT:
Should a patient alarm condition for SpO_2 or pulse rate occur, the Monitor will indicate an alarm condition (flashing & beeping) while continuing to monitor and display the patient's current SpO_2%. The alarm will automatically reset when the patient's condition returns to within the preset alarm parameters.

DURING SpO_2 MEASUREMENT:
Should a patient alarm condition for SpO_2 or pulse rate occur, the operator may invoke "Silence Mode" by pressing the SILENCE button. This will silence the audible tone (display will continue to flash), while the practitioner attends to the patient and Monitor. Silence mode resets automatically after 30 seconds, or when the patient's condition returns to within the preset alarm parameters.

Note: Certain alarms alert the operator to abnormal system conditions or internal system failures. Alarm conditions, error codes and suggested operator action are reviewed in the Troubleshooting section (Section V.1.) of this manual.

IV. 6. SETTING THE INFLATION PRESSURE PRESET LEVEL

The default cuff inflation level for blood pressure measurements is set in the Monitor's internal configuration menu. The factory default level is 160 mmHg. If desired, the default pressure preset can be changed by following theses instructions:

- Turn the monitor off.
- Press both the POWER button and the START button simultaneously. The Monitor will enter it's internal configuration mode.
- Press the REVIEW button 6 times. "PrP" will appear in the systolic display, and the default pressure preset level will appear in the diastolic display.
- Press the ADJUST button to cycle through the seven options available: 120, 140, 160, 180, 200, 240 and 280 mmHg.
- When the desired pressure preset level is illuminated, press the REVIEW button once to save this change.
- Turn the Monitor off.
- When the Monitor is turned on, the new pressure preset will be established as the default level. The Monitor will always revert to this pressure preset level on power up.

During normal operation, the operator may choose to change the pressure preset level to accommodate a specific patient need. However, any pressure preset change will not be retained in memory after the Monitor has been turned off.

To change the pressure preset during normal operation, press the PRESSURE PRESET button. The SYSTOLIC display will show the current pressure preset level in mmHg.

To change the inflation pressure, press the PRESSURE PRESET button again. Each press of the PRESSURE PRESET button will cause the display to cycle through the seven available options; 120 mmHg, 140 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 240 mmHg, 280 mmHg. When the desired pressure preset level is displayed, pressing any other button or refraining from pressing the PRESSURE PRESET button for 10 seconds will save the displayed pressure preset level, and the Monitor will return to normal operating mode.

The new pressure preset value will remain in memory only while the Monitor is turned on. When the Monitor is turned off, the pressure preset will revert to the default pressure established in the Monitor's internal configuration mode.

Note: In Manual Blood Pressure Operating Mode, the Monitor will inflate to the level determined by the pressure preset. However, if a BP measurement is initiated within one minute of a prior BP measurement, the Monitor will inflate to a level which is 40 mmHg above the previous systolic reading.

In Automatic Blood Pressure Operating Mode, the Monitor will inflate to the level determined by the pressure preset for the initial BP determination only. After the initial measurement, the Monitor will inflate to a level which is 40 mmHg above the previous systolic reading.

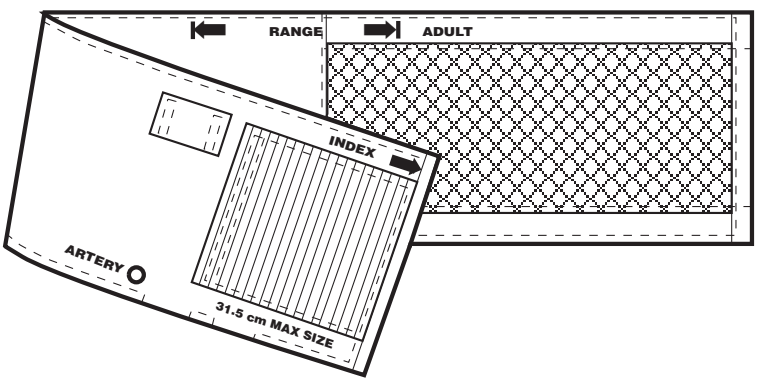
IV. 7. BLOOD PRESSURE CUFF SELECTION CRITERIA

Careful sizing of the cuff is important to the accuracy of blood pressure readings. If the cuff is too small, the readings could be falsely high.

There are two simple methods for determining the correct cuff size for the patient. Use either method (A) or (B) below.

(A) DETERMINING CUFF SIZE WITH THE CUFF MARKINGS

One way to insure proper cuff size is to wrap the cuff around the patient's upper arm and visually check it. The cuff is marked with a distinct white edge and two divisions that indicate "range." When the cuff is properly fit, the edge will meet the cuff at some point within the range. See illustration below.



(B) CHART FOR DETERMINING CUFF SIZE

You can also determine cuff size by measuring the patient's arm circumference midway between the elbow and shoulder, and then use the chart below to select the correct cuff.

CUFF SIZE	ARM CIRCUMFERENCE	
	INCHES	CENTIMETERS
Small	4.7 - 8.3	12.0 - 21.0
Medium	7.1 - 12.6	18.0 - 32.0
Large	8.3 - 15.4	21.0 - 39.0
Extra-Large	11.8 - 18.5	30. - 48.0

IV. 8. POSITIONING THE BLOOD PRESSURE CUFF

The preferred blood pressure measurement site for adults and children is the upper arm. The arm must be relaxed and motion-free during measurement(s).

Warning: Do not place the cuff on any extremity being used for intravenous infusions, or any area where circulation is or may be compromised.

Warning: Do not place the cuff on any extremity being used for SpO_2 monitoring. Cuff inflation during an SpO_2 measurement will cause inaccurate SpO_2 results.

Wrap the cuff snugly with room between the cuff and the arm for two fingers. Excessive tightness may cause venous congestion and discoloration of the limb. If the cuff is wrapped too loosely, it cannot be inflated properly and the measured values may be in error.

It is best to place the cuff on a bare arm. Clothing may interfere with measurement accuracy.

When wrapping the cuff, observe the mark on the cuff which must be placed over the artery. Insure that the hose is not twisted, kinked or compressed, as this may cause measurement errors.

IV. 9. MANUAL MODE BLOOD PRESSURE

Blood pressure measurement may be initiated on demand by the operator. This is the manual mode of operation.

To operate the blood pressure monitor in manual mode, follow this procedure:

1. Insure that the blood pressure cuff is properly sized and wrapped around the patient's upper arm (or alternate site, as necessary).

2. With the Monitor powered up, press the START button. The Monitor will inflate the cuff to the level determined by the operator as the pressure preset.

3. The systolic display will show the pressure in the cuff as the blood pressure determination is being made.

4. When the measurement cycle is complete an audible tone will sound and the systolic, diastolic and pulse rate* display will show the values of the reading.

5. The reading will be displayed for two minutes, and then this display will be blanked. The reading may be recalled at any time prior to the next BP determination by pressing the REVIEW button.

6. Pressing CANCEL at any time during a blood pressure determination will cause the determination to be aborted, and the cuff to rapidly deflate.

*Pulse rate, as determined from the blood pressure measurement method, will be displayed with the BP reading only if SpO_2 option is absent or disabled. If the SpO_2 function is operational, all pulse rate determinations will come as a result of the SpO_2 measurement method.

IV. 10. AUTOMATIC MODE BLOOD PRESSURE

Blood pressure measurements may be automatically initiated at operator programmed time intervals.

To operate the blood pressure monitor in automatic ("Auto") mode, follow this procedure:

1. Insure that the blood pressure cuff is properly sized and wrapped around the patient's upper arm (or alternate site, as necessary).

2. Press the AUTO button and note two dashes "--" in the CYCLE display. This is the default setting for AUTO mode and indicates that no time interval cycles have been selected.

3. Select one of the ten pre-programmed cycle interval times by pressing the AUTO button until the desired interval time (in minutes) is displayed. The operator may choose from the following time interval selections: 1, 3, 4, 5, 10, 15, 30, 45, 60 or 90 minutes. Note: These intervals represent the time from the *beginning* of one cycle to the *beginning* of the next cycle. Note: In 1-minute automatic cycle mode, the Monitor will automatically take BP measurements in 1 minute intervals for up to 15 minutes.

The operator may also choose "St", *STAT* mode. In *STAT* mode the Monitor takes blood pressure readings repeatedly for up to 15 minutes. A new measurement cycle will be initiated when the cuff pressure from the previous cycle drops below 10mmHg.

4. When the desired interval is displayed, the operator may select the interval by pressing any other button or by refraining from pushing the AUTO button for 10 seconds. When the interval is stored, the AUTO indicator light will glow green.

5. The unit will take its first automatic blood pressure determination 10 seconds after the time interval is selected. Subsequent readings will be taken according to the time interval selected.

6. For the first automatic blood pressure determination, the Monitor will inflate the cuff to the level determined by the operator as the pressure preset. For all subsequent blood pressure determinations, the Monitor will inflate the cuff to a pressure 40 mmHg above the prior systolic reading.

7. The systolic display will show the pressure in the cuff as the blood pressure determination is being made.
Exception: *In STAT mode, the systolic and diastolic displays will show the most current completed BP measurement.*

8. When the measurement cycle is complete an audible tone will sound and the systolic, diastolic and pulse rate* displays will show the values of the reading.

9. The measurement will be displayed until the next measurement cycle is initiated.

10. Pressing CANCEL at any time during a blood pressure determination will cause the determination to be aborted, and the cuff to deflate. In STAT mode, pressing CANCEL will also terminate the STAT mode of operation.

11. To end an AUTO blood pressure session, press the AUTO button until two dashes "--" appear in the CYCLE display. Auto mode will then be terminated. *STAT* mode may be terminated in this manner, or by pressing the CANCEL button.

*Pulse rate, as determined from the blood pressure measurement method, will be displayed with the BP reading only if the SpO_2 option is absent or disabled. If the SpO_2 function is operational all pulse determinations will come as a result of the SpO_2 measurement method.

IV. 11. REVIEWING INFORMATION FROM PRIOR CYCLES

The Welch Allyn Vital Signs Monitor will hold in memory the previous 99 sets of vital signs data which include blood pressure, pulse rate and/or temperature and/or SpO_2. The information is held in memory until the Monitor is turned off. When memory capacity (99 sets of data) has been reached, the MEMORY indicator will blink. After capacity is reached, the oldest stored reading will be deleted to make room for the newest data set.

The following criteria are applied for saving data:

Blood Pressure Data: will be saved for both MANUAL and AUTOMATIC cycles.

Predictive Temperature Data: will always be saved.

Monitor Mode Temperature Data: will be saved only if concurrent with a blood pressure cycle.

SpO_2 Data: will be saved if concurrent with a blood pressure cycle, or a predictive temperature measurement. Will be saved if the START button is pressed while the BP mode is inactive. Will also be saved (one data set per minute) if a patient alarm condition occurs.

Pulse Rate Data: will be saved with every blood pressure and SpO_2 data set.

To review data from prior vital signs measurements, press the REVIEW button. The most recently obtained data will appear in the appropriate displays, and the CYCLE display will show the total number of data sets currently in memory. Also, the MEMORY indicator will be illuminated, indicating that stored data is being displayed.

Each subsequent press of the REVIEW button will display the next most recent data set. After the earliest data set has been displayed (CYCLE display = 1) the next press of the REVIEW button will return the display to the most recent set of measurements. At any time during REVIEW the operator may return to normal operating mode by pressing any other button or by refraining from pressing the REVIEW button for 10 seconds.

IV. 11. A. “ERASE DATA” FUNCTION

The CANCEL button may be used to erase all stored blood pressure, pulse rate, oxygen saturation and temperature data, without turning the Monitor off.

To erase all stored data in the Welch Allyn Vital Signs Monitor, press and hold the CANCEL button for three (3) seconds until a confirmatory beep is heard. This beep indicates that all data stored in the Monitor has been erased.

Data is also erased each time the Welch Allyn Vital Signs Monitor is turned off.

IV. 12. SELECTING THE TEMPERATURE SCALE

The temperature module option of the Welch Allyn Vital Signs Monitor is capable of displaying temperature in either degrees Fahrenheit (°F) or degrees Celsius (°C).

To determine the current temperature scale, remove the temperature probe from its holder and view the TEMPERATURE display. A small green display will illuminate showing either "°F" or "°C."

To change the temperature scale, the user must enter the Monitor's internal configuration mode:

1. While the Monitor is turned off, press both the POWER and START buttons simultaneously. Hold the START button down until all of the LED display segments are illuminated.

2. The operator can now cycle through the Monitor's internal configuration menu by pressing the REVIEW button. Pressing the REVIEW button three times will cycle to the temperature options and three dashes (---) will appear in the TEMPERATURE display.

3. The first option illuminated on the TEMPERATURE display is "°F." Pressing the ADJUST button twice will illuminate "°C." When the desired temperature scale is selected, press the REVIEW button again and then turn the Monitor off. By following this procedure, the selected temperature scale will be saved into memory.

IV. 13. SELECTING TEMPERATURE OPERATION MODE

When configured with the temperature option the Welch Allyn Vital Signs Monitor has the capability of taking a temperature in either Normal or Monitor mode.

In the Normal mode the thermometer's microprocessor "predicts" body temperature in about 4 seconds for oral temperatures and in about 15 seconds for rectal temperatures.

Monitor mode is normally used for longer term monitoring and when difficult situations prevent accurate temperature from being taken in the Normal mode. In Monitor mode, the probe must be in contact with tissue for at least 3 minutes for accurate temperature measurement.

Note: Axillary temperatures may only be taken in Monitor mode.

The default setting for the LifeSign Monitor is Normal mode.

To change the operating mode for temperature determinations, the user must enter the Monitor's internal configuration mode:

1. While the Monitor is turned off, press both the POWER and START buttons simultaneously. Hold the START button down until all of the LED display segments are illuminated.

2. The operator can now cycle through the Monitor's internal configuration menu by pressing the REVIEW button. Pressing the REVIEW button three times will cycle to the temperature options, and three dashes (---) will appear in the TEMPERATURE display.

3. Press the ADJUST button once to choose Monitor mode (°F), or three times to choose Monitor mode (°C). When the desired selections are made, press the REVIEW button again and then turn the Monitor off. These choices will be saved into memory.

Note: If the temperature is in Normal mode, the user may easily switch to Monitor mode without entering the Monitor's internal configuration mode. To do this, remove the probe from the probe holder, attach a new probe cover, and wait one minute (do not place probe in patients mouth or rectum at this time). After one minute the Monitor will automatically switch to temperature Monitor mode, and the green "Monitor Mode" display will be illuminated on the temperature display. The operator may now proceed to take the patient's temperature. After the probe is replaced in the holder, the Monitor will revert back to Normal temperature mode.

Note: Before a temperature probe can be used by the Monitor it must first be "characterized". This is done automatically when the probe is connected to the Monitor and placed in its holder. During probe characterization, the temperature display will show the letters "PC". Temperature measurements may not be taken during probe characterization. Attempting to take a temperature reading while "PC" is displayed will case an error condition. When probe characterization is complete, the temperature display will be blank. A temperature reading may then be initiated.

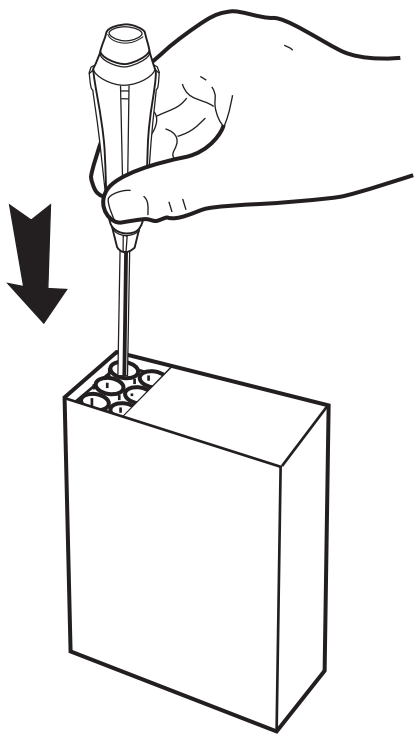
IV. 14. TAKING AN ORAL TEMPERATURE

To take an oral temperature (in either Normal or Monitor mode) follow this procedure:

1. Insure that the oral probe is connected to the unit. The oral probe has a BLUE tip. Accurate oral temperatures can only be obtained by using the blue temperature probe.

2. Remove the probe from the probe holder. A short self-test mode will be initiated where every LED segment on the TEMPERATURE display is illuminated briefly. Following this self-test the display will show "OrL". "OrL" = Oral Probe indicating that the oral probe is in use.

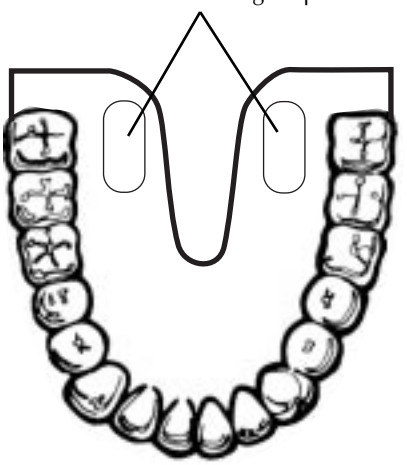
3. Load a probe cover onto the probe by holding the probe collar with the thumb and forefinger, being careful not to hold or press the ejection button. See illustration below.



Loading the probe cover

4. Insert the probe tip gently into the patient's slightly opened mouth. Carefully slide the probe under the tongue on either side of the mouth to reach the sublingual pocket (see illustration below). Accurate temperatures can only be obtained in this location. Temperatures in other mouth locations can vary by as much as 2°F or 1°C.

Location of the sublingual pockets



5. **The probe should be held by the clinician during the entire temperature measurement process to insure the probe tip maintains tissue contact.**

6. During the temperature measurement cycle the TEMPERATURE display will show a series of LED segments in a box - shaped formation. This indicates that the temperature measurement is in process.

7. When the final temperature has been reached a tone will sound and the temperature will be displayed on the Monitor.

8. After the temperature measurement is complete, remove the probe from the patient's mouth and eject the probe cover by firmly pressing the ejection button on the probe. Properly dispose of the used probe cover.

9. Insert the probe into the probe holder before attempting to take another temperature measurement.

10. The current temperature is displayed for one minute after the probe is replaced in the holder, after which time the display will go blank. The most recent temperature can be recalled by pressing the REVIEW button once.

Note: If a probe position error occurs during the temperature determination, the temperature display will alternate between the final predicted temperature and the letter "P" in the display.

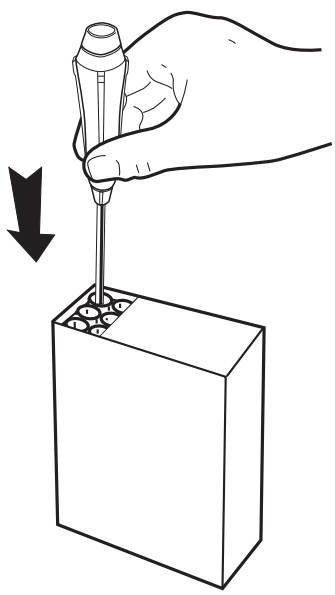
IV. 15. TAKING A RECTAL TEMPERATURE

To take a rectal temperature (in either Normal or Monitor mode) follow this procedure:

1. Insure that the rectal probe is connected to the unit. The rectal probe has a RED tip. Accurate rectal temperatures can only be obtained by using the red temperature probe.

2. Remove the probe from the probe holder. A short self-test mode will be initiated where every LED segment on the TEMPERATURE display is illuminated briefly. Following this self-test the display will show "rEC". "rEC" = Rectal Probe indicating that the rectal probe is in use.

3. Load a probe cover onto the probe by holding the probe collar with the thumb and forefinger, being careful not to press the ejection button. See illustration below.



Loading the probe cover

4. Separate the buttocks with one hand. Apply a thin coat of water-based lubricant when necessary. Using the other hand, gently insert the probe ONLY 1cm (3/8 inch ONLY) inside the rectal sphincter. Extreme caution should be used to avoid risk of bowel perforation in children.

5. Tilt the probe to insure good tissue contact and continue to keep the buttocks separated while the measurement is in process.

6. During the temperature measurement cycle, the TEMPERATURE display will show a series of LED segments in a box-shaped formation. This indicates that the temperature measurement is in process.

7. When the final temperature has been reached, a tone will sound and the temperature will be displayed on the Monitor.

8. After the temperature measurement is complete, remove the probe from the patient's rectum and eject the probe cover by firmly pressing the ejection button on the probe. Properly dispose of the used probe cover.

9. Insert the probe into the probe holder before attempting to take another temperature measurement.

10. The current temperature is displayed for one minute after the probe is replaced in the holder, after which time the display will go blank. The most recent temperature can be recalled by pressing the REVIEW button once.

Note: If a probe position error occurs during the temperature determination, the temperature display will alternate between the final predicted temperature and the letter "P" in the display.

IV. 16. SpO_2 OPERATION MODE

The Welch Allyn Vital Signs Monitor incorporates either the Nonin® pulse oximetry module or the Nellcor Puritan Bennett™ pulse oximetry module. The pulse oximeter determines arterial oxyhemoglobin saturation (SpO_2%) by measuring the absorption of red and infrared light passed through the tissues. Changes in absorption caused by pulsation of blood in the vascular bed are used to determine arterial saturation and pulse rate.

Oxygen saturation percent is calculated with each pulse detected, and thus the Monitor display is continually updated. The pulse signal bar graph is an indicator of the strength and quality of the detected pulses.

SpO_2 is generally measured via pulses detected using a finger clip sensor. However, for certain situations SpO_2 may be measured at alternate sites including the earlobe, forehead and toes. Special sensors must be employed in these situations (See Appendix A for Nonin® sensors, Appendix B for Nellcor Puritan Bennett™ sensors).

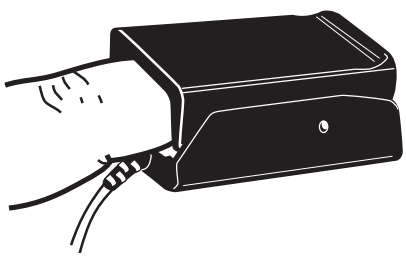
IV. 16. A. USING THE FINGER CLIP SENSOR

Warning: Only Nonin® brand SpO_2 sensors and accessories should be used with Welch Allyn Vital Signs Monitors configured with the Nonin® pulse oximetry option. Only Nellcor Puritan Bennett™ brand SpO_2 sensors and accessories should be used with Welch Allyn Vital Signs Monitors configured with the Nellcor Puritan Bennett™ pulse oximetry option.

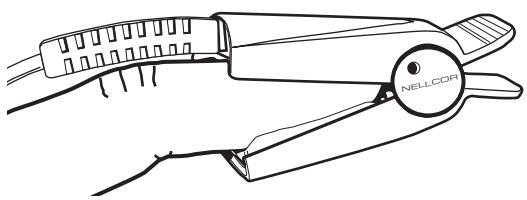
The reusable finger clip pulse oximeter sensor is designed for spot-check monitoring of arterial oxyhemoglobin saturation (SpO_2%).

The finger clip sensor may also be used for continuous monitoring where patient movement is not expected and the patient's finger is large enough for the sensor to fit securely. The Nonin finger clip sensor (5200-40, 5200-54) may be used for continuous monitoring less than 30 minutes. The Nellcor Puritan Bennett finger clip sensor (DS-lOOA) may be used for continuous monitoring less than 4 hours.

To use the finger clip sensor, insert the patient's finger (preferably the left or right index finger) completely into the sensor as shown. The thumb is specifically not recommended for use with the finger clip sensor.



The Nonin® Finger Clip Sensor
(5200-40, 5200-54)



The Nellcor Puritan Bennett™ Finger Clip Sensor
(DS-100A)

Warning: If blood pressure monitoring is occuring simultaneously, insure that the finger clip SpO_2 sensor is attached to the limb opposite the limb with the blood pressure cuff.

Note: Sensor sites must be checked periodically to determine circulation, sensor positioning and skin sensitivity.

IV. 16. B. OTHER SENSORS

A wide variety of reusable and disposable pulse oximetry sensors are available for use with the Welch Allyn Vital Signs Monitor. These sensors expand the utility of the pulse oximetry component of the monitor.

For a detailed description of the use and application of these sensors, see Appendix A of this manual for Nonin® sensors, Appendix B for Nellcor Puritan Bennett™ sensors.

Warning: Use only Nonin® brand SpO_2 sensors and accessories with Welch Allyn Vital Signs Monitors configured with Nonin® pulse oximetry module. Use only Nellcor Puritan Bennett™ brand SpO_2 sensors and accessories with Welch Allyn Vital Signs Monitors configured with the Nellcor Puritan Bennett™ pulse oximetry module.

IV. 16. C. TAKING AN SpO_2 MEASUREMENT

Prior to taking an SpO_2 measurement, insure that the SpO_2 mode of the Welch Allyn Vital Signs Monitor is functional. This will be indicated by a glowing green indicator to the left of the SpO_2 MODE button, and 2 dashes "--" in the SpO_2 display.

The operator should follow this procedure for taking an SpO_2 measurement:

1. Properly attach the appropriate sensor to the patient.

2. The pulse signal bar graph will illuminate, indicating the relative strength and quality of the patient's pulses at the sensor site. The sensor takes approximately 10 seconds to determine the initial SpO_2% value and pulse rate. When the initial values are determined they will be shown in the SpO_2 display and the Pulse Rate display respectively.

3. The SpO_2% and pulse rate are updated approximately every second.

4. Removing the SpO_2 sensor from the patient ends the monitoring period and immediately blanks the pulse signal bar graph. The SpO_2 display will flash 2 dashes "--" and a repetitive audible alarm will sound. To reset the sensor removal alarm, press any button on the Monitor's display.

Note: If the programmable alarms for low SpO_2%, high pulse rate and low pulse rate are turned off, no sensor removal alarm will occur when the SpO_2 sensor is removed from the patient.

IV. 17. PRINTER OPERATION

The Welch Allyn Vital Signs Monitor may be configured with an optional integrated thermal printer.

The operator may control the printer using the two buttons (FEED, PRINT) located on the top rear face of the Monitor.

Pressing the FEED button advances the paper.

The PRINT button will generate the printout of all the stored blood pressure, temperature, pulse rate and SpO_2 data in the Monitor. The unit will store and print a maximum of 99 data sets.

The following criteria are applied for saving and printing measurement data:

Blood Pressure Data: will be saved for both MANUAL and AUTOMATIC cycles.

Predictive Temperature Data: will always be saved.

Monitor Mode Temperature Data: will be saved only if concurrent with a blood pressure cycle.

SpO_2 Data: will be saved only if concurrent with a blood pressure cycle, or a predictive temperature measurement. Will be saved if the START button is pressed and the BP mode has been disabled. Will also be saved (one data set per minute) if a patient alarm condition occurs.

Pulse Rate Data: will be saved with every blood pressure and SpO_2 data set.

Note: If no data is stored in the Monitor, pressing the PRINT button will cause only the printout header to be printed.

IV. 17. A. PRINTING OPTIONS: BATCH PRINT OR STREAMING PRINT MODE

The operator may choose to print all stored data in either batch print mode (all stored data printed simultaneously) or streaming print mode (data printed automatically at the time it is stored). Batch print mode is the default setting for the Welch Allyn Vital Signs Monitor.

To change the print mode, press both the START button and the POWER button simultaneously. This activates the Monitor's internal configuration mode. After all of the current software versions are displayed on the Monitor, press the REVIEW button 7 times. The current print mode will appear in the systolic and diastolic displays as either "bAt Pr" (batch print mode) or "Str Pr" (streaming print mode). Press the ADJUST button to toggle between the two print mode choices. When the desired print mode is displayed, press the REVIEW button again, then turn the Monitor off. Turn the Monitor on by pressing the POWER button. The desired printing mode will now be operational.

If batch print mode is chosen, all data in the Monitor's memory will be printed whenever the PRINT button is pressed.

If streaming print mode is chosen, the printer must be activated after the Monitor is turned on. Press the PRINT button and "Pr Str On" will appear in the systolic, diastolic and pulse rate displays as the print header is printed. Patient information will now automatically print whenever data is stored into the memory of the Monitor. To turn the streaming print function off, press the PRINT button again. "Pr Str Off" will appear in the systolic, diastolic and pulse rate displays.

A batch printout may be initiated while in streaming print mode. First turn the streaming print function off by pressing the PRINT button. "Pr Str Off" will appear in the systolic, diastolic, and pulse rate displays. Next, press and hold the PRINT button for 3 seconds. A batch printout will be printed.

IV. 18. USING THE RS232 COMPUTER INTERFACE

The Welch Allyn Vital Signs Monitor includes an external RS232 Computer Data Interface Connector. With this option the user has the ability to upload stored data from the Monitor to a computer or network. Also, any user programmable options may be programmed via the computer.

For more detailed information on using the RS232 compatable interface, contact Welch Allyn Customer Service.

IV. 19. MEAN ARTERIAL PRESSURE (MAP)/DATA SEND MODE/DATA STREAM MODE

The operator has the ability to activate the ADJUST button to perform additional functions. These functions are mutually exclusive, and include:

- The ability to display the Mean Arterial Pressure (MAP) when ADJUST is pressed.
- The ability to send patient data to the Monitor's serial port when ADJUST is pressed.
- The ability to stream patient data to the Monitor's serial port whenever patient data is stored into the Monitor's memory.

To activate the additional functionality of the ADJUST button, press both the START button and the POWER button simultaneously. This activates the Monitor's internal configuration mode. After the current software versions are displayed on the Monitor, press the REVIEW button 6 times. The current functionality of the ADJUST button will appear in the systolic and diastolic displays. Use the ADJUST button to toggle through the four choices.

When the desired functionality is displayed, press the REVIEW button, then turn the Monitor off. To turn the Monitor on, press the POWER button. The desired functionality of the ADJUST button will now be operational.

"no Op" (no operation) indicates that the ADJUST button has no additional functionality. This is the default mode of the Welch Allyn Vital Signs Monitor.

"NAP" (MAP-Mean Arterial Pressure) indicates that pressing the ADJUST button will cause the Mean Arterial Pressure (in mmHg), to be displayed and printed while a valid blood pressure measurement is displayed. Mean Arterial Pressure data cannot be sent to the serial port.

"SEn dAt" (Send data) indicates that pressing the ADJUST button sends patient data to the Monitor's serial port. In normal mode, the most recent data set is sent to the serial port when the ADJUST button is pressed. In REVIEW mode, the currently displayed data set is sent to the serial port when the ADJUST button is pressed.

"Str dAt" (Stream data) indicates that streaming data mode is functional. This mode allows patient data to be sent to the serial port automatically whenever such data is stored into the Monitor's memory. To initiate streaming data mode during normal operation, press the ADJUST button. "Str On" in the systolic and diastolic displays indicate that streaming data mode is operational. To turn streaming data mode off, press ADJUST again. "Str Off" in the systolic and diastolic displays indicates that streaming data mode is no longer operational.

SECTION V
TROUBLESHOOTING/ MAINTENANCE/CALIBRATION

1. Troubleshooting: Error Indications and Interpretation
2. Maintenance
    a. Cleaning
    b. Storage
    c. Battery Removal and Replacement
3. Calibration
    a. Blood Pressure Calibration Check
    b. Temperature Calibration Check
    c. SpO_2 Calibration Check

V. 1. TROUBLESHOOTING: ERROR INDICATIONS AND INTERPRETATION

The following table of alarm conditions and error codes is intended to provide the operator with a quick reference to the descriptions and probable causes of the error codes. For service level troubleshooting, refer to the service manual.

When responding to a Monitor alarm, always CHECK THE PATIENT FIRST and then proceed to check the Monitor.

Press CANCEL to reset patient alarm conditions.

ERROR CODE	MEASUREMENT MODE	DESCRIPTION	CORRECTIVE ACTION
C01	Blood Pressure	Measurement cycle was cancelled by operator	-------
C02	Blood Pressure	Autozero Failure	Check for air obstruction, limit patient movement
C03	Blood Pressure	Inflation too rapid obstruction	Check for kinked hose or air
C04	Blood Pressure	Excessive inflation time	Check for air leaks
C05	Blood Pressure	Excessive noise	Check patient condition, cuff placement, limit patient movement
C06	Blood Pressure	Measurement was outside of Monitor's measurement range	Check patient condition
E10	Blood Pressure	Cuff overpressure condition	Check patient condition
C20	Temperature	Broken/missing probe	Replace probe
C21	Temperature	Probe not ready	Replace probe in holder, wait 15 seconds, retry
E0.0 thru E9.9	Temperature	Internal malfunction	Contact customer service
"P"	Temperature	Loss of tissue contact	Insure proper probe positioning
"PC"	Temperature	Probe characterization in process	Do not remove probe while displayed

ERROR CODE	MEASUREMENT MODE	DESCRIPTION	CORRECTIVE ACTION
"--"	SpO_2	Sensor Error	Check patient condition, sensor position and connection
E7	SpO_2	Internal Malfunction	Contact customer service.
E11	General	Internal safety violation	Check patient, contact customer service
E12	General	Ambient temperature out of range	Adjust temperature or monitor location
E13	General	Battery failure	Use wall transformer
E20 thru E50	General	Internal malfunction	Contact customer service

V.2. A. MAINTENANCE: CLEANING

The Welch Allyn Vital Signs Monitor may be wiped clean with a cloth slightly dampened with warm water and a mild detergent solution. Never immerse the monitor in any type of fluid.

Occasionally, as necessary, the unit may be cleaned with appropriately diluted non-staining disinfectant solution.

Note: Care should be taken to prevent water or other fluids from entering any connectors. Should this occur, the connectors should be dried with warm air. All monitoring functions should then be checked for proper operation.

The reusable blood pressure cuff should be cleaned by sponging with a damp cloth. If washing is necessary, the bladder should be removed and the cuff washed with soap or detergent/disinfectant. After washing, the cuff should be air dried.

Cabling and the pressure hose can be wiped with a damp cloth moistened in a mild detergent solution. Do not immerse hoses.

The temperature probe should periodically be cleaned by wiping with an alcohol-dampened cloth or wipe, warm water, or properly diluted non-staining disinfectant. Do not immerse the probes.

The Nonin® reusable finger clip SpO_2 sensor may be cleaned with isopropyl alcohol solution, and may be sterilized using ethylene oxide (EtO), cold cycle. Do not immerse the sensor.

The Nellcor Puritan Bennett™ reusable finger clip SpO_2 sensor may be cleaned with 70% alcohol or 1:10 bleach.

V. 2. B. MAINTENANCE: STORAGE

Whenever possible, the Welch Allyn Vital Signs Monitor should be stored at room temperature in a dry environment.

If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping carton.

Note: Insure that the printer is loaded with paper prior to storage.

Storage specifications are as follows:

Temperature: -20°C to +50°C
-4°F to +122°F

Relative Humidity: 15-95% (non-condensing)

V. 2. C. MAINTENANCE: BATTERY REMOVAL & REPLACEMENT

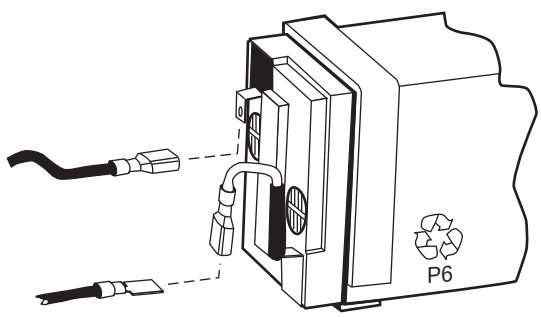
Occasionally it may be necessary for the internal battery to be replaced. When the battery will no longer take a charge, remove it and replace it as outlined below, with a battery of the same part number.

1. Insure that the AC power transformer cord is disconnected from the Monitor, and that the Monitor is turned off.

2. Use a Phillips-head screwdriver to remove the four (4) screws holding in the battery door. Remove the battery door exposing the battery.

3. Tip the Monitor and slide the battery out. Disconnect each of the 2 connectors and discard the old battery per local regulations.

4. Attach the battery connectors to the new battery as shown below.



Attaching connectors to the new battery.

5. Slide the new battery into the battery compartment as far as it will go. The battery terminals should be aligned as shown on the label inside the battery compartment.

6. Replace the battery door, tightening each of the (4) screws.

7. Connect the AC power transformer to the monitor and allow the new battery to charge for approximately 16 hours. The Monitor may be used during this charging period. While charging, the charging indicator will flash a yellow light. When the Monitor is fully charged, the flashing light will be replaced with a solid yellow light.

V. 3. A. CALIBRATION: BLOOD PRESSURE CALIBRATION CHECK

The accuracy of the Welch Allyn Vital Signs Monitor's pressure measurement can be verified with an accurate office mercurial or aneroid sphygmomanometer. The calibration check is a simple yet valuable test to determine that the unit is sensing pressure accurately. Welch Allyn recommends that blood pressure calibration be verified on an annual basis.

Equipment needed:
1. Accurate* office sphygmomanometer with inflation system
2. Calibration T-connector
3. Any rigid cylinder that approximates arm size (such as a one-pound coffee can)

Disconnect the coiled tubing from the cuff. Attach the calibration T-connector to the coiled tubing end. Connect the male taper connector extending from the tubing of the office sphygmomanometer into the large, open end of the T-connector. Then connect the female taper connector extending from the office sphygmomanometer cuff to the other side of the T-connector. Wrap the arm cuff around the rigid cylinder. Check that all connections are tight.

Initiate the Monitor's internal configuration settings menu by powering up the unit while the START button is depressed. Hold the START button down until all the LED display segments go off. The first message displayed is the revision level of the internal software. This will be displayed in the systolic and diastolic displays. Press the REVIEW button to advance to the calibration check menu. Once in the calibration check menu, the display will read "CAL" in the systolic display and the pressure will be shown in the diastolic and pulse rate displays.

Press the START button to close the Monitor's internal valve. Inflate the cuff manually to a pressure of about 250 mmHg by squeezing the manometer bulb. (If the cuff won't inflate, insure that the valve on the bulb is fully closed and that you have pressed the START button to close the Monitor's internal valve). Now, slowly deflate the cuff and stop at 30mmHg increments to compare the pressure reading on the manometer with the pressure reading displayed on the Monitor display.

The Monitor displays the pressure in mmHg units, down to the .01 mmHg resolution. This should compare closely with the manometer reading, within 3 mmHg. (Inherent inaccuracies of ±3mmHg in office sphygmomanometers could result in an observed and acceptable Monitor error of ±6mmHg).

Compare several readings taken at pressures ranging from 250 to 50 mmHg. This checks the Monitor within the range of typical blood pressure readings. If the Monitor does not agree closely with the manometer, that is within ±3 mmHg, call the Welch Allyn technical service center.

WARNING: Internal safety features of the Monitor will automatically open the valve and sound an alarm if the pressure is detected to be above 15 mmHg for longer than 165 seconds. In the event that this happens pressing either the SILENCE or CANCEL button will reset the alarm condition. Pressing the START button will then close the valve after which the check can be continued.

Upon completion of the calibration check, the Monitor can be powered down and powered back up to bring the device to its normal state of operation.

*Meets O.E.M. product specifications and at minimum +2mmHg.

V. 3. B. CALIBRATION: TEMPERATURE CALIBRATION CHECK

The accuracy of the Welch Allyn Vital Signs Monitor temperature determinations can be verified using the Temperature Calibration Key. The calibration check is a simple yet valuable test to determine that the unit is measuring temperature accurately.

1. Turn the Monitor on by pressing the POWER button.
Note: The temperature function will automatically go into Monitor Mode as part of this procedure.

2. Remove the temperature probe completely form the holder and insert the temperature calibration key.

3. Insert, then remove the probe from the probe holder to reset the thermometer.

4. Wait for the temperture display test to be complete. Observe and record the temperture noted on the temperature display.

5. The recorded temperature should be 97.3°F ± 0.2°F (36.3°C +/- 0.1° C) if the Monitor is properly calibrated. If the temperature displayed is out of this range, call your Welch Allyn technical service center for assistance.

V. 3. C. CALIBRATION: SpO_2 CALIBRATION CHECK

The accuracy of the Welch Allyn Vital Signs Monitor's SpO_2 determinations can be verified using the SpO_2 Calibration Finger Phantoms. The calibration check is a simple yet valuable test to determine that the unit is measuring SpO_2 accurately.

Caution: The SpO_2 simulation by the Finger Phantom is temperature dependant. Allow the Monitor and the Finger Phantoms to stabilize at room temperature for at least one hour before using.

Caution: The Finger Phantoms are date-coded. Check the expiration date before using.

Note: To check the calibration over the full range of SpO_2 determinations, follow this procedure with each of the three Finger Phantoms.

1. Insure the SpO_2 sensor is properly connected to the Monitor.

2. Place a Finger Phantom in the slot of the holder.

3. Attach the SpO_2 sensor to the tip of the Finger Phantom. Insure that the emitting and detecting diodes are vertically aligned and in direct contact with the Finger Phantom.

4. Route the sensor cable in such a way that it does not influence the sensor attachment. For sensors with cables directed to the back of the finger, route the cable through the notches in the bottom of the holder.

5. Turn the Monitor on by pressing the POWER button.

6. Lightly tap the flat area of the Finger Phantom at a rate of 80 ± 10 beats per minute. Allow the SpO_2 to stabilize. This should take approximately 15 to 30 seconds.

7. Record the displayed SpO_2 and pulse rate values, as well as the ambient temperature.

8. SpO_2 values should be ± 3.0% of the value shown on the Finger Phantom if the Monitor is properly calibrated. If the SpO_2 displayed is out of this range, call your nearest Welch Allyn technical service center for assistance.

SECTION VI
WARRANTY AND SERVICE INFORMATION

1. Warranty Information
2. Service Information
    a. Service Policy
    b. Technical Assistance/Service Centers
    c. Service Manual/Spare Parts
    d. Service Loaners

VI. 1. WARRANTY INFORMATION

Welch Allyn warrants the Welch Allyn Vital Signs Monitor, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents. (Pulse oximetry sensors and temperature probes are warranteed for one year). Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the instrument to Welch Allyn or an authorized distributor, agent or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

RETURN THE INSTRUMENT REGISTRATION CARD

IMPORTANT!
Remember to submit the instrument registration card for warranty validation. Complete the information and mail the pre-addressed card to Welch Allyn.

VI. 2. A. SERVICE INFORMATION: SERVICE POLICY

All repairs on products under warranty must be performed or approved by a Welch Allyn Service Center. *Unauthorized repairs will void the warranty*. Products out of warranty should be repaired by qualified electronics personnel or a Welch Allyn Service Center.

VI. 2. B. SERVICE INFORMATION: TECHNICAL ASSISTANCE

If you have an equipment problem that you cannot resolve, call the Welch Allyn Service Center nearest you for assistance. Technical service support is available to you by telephone on normal business days at the phone numbers listed below.

If you are advised to return a product to Welch Allyn for service or repair, schedule the repair with the service center nearest you.

Before returning a product for repair you must obtain authorization from Welch Allyn. An RGA (Return Goods Authorization) number will be given to you by our service personnel. Be sure to note this number on the outside of your shipping box. Returns without an RGA number will not be accepted for delivery.

WELCH ALLYN SERVICE CENTERS

For Service or Repair

USA Customers
Welch Allyn Inc.
Technical Service Center
95 Old Shoals Road
Arden, NC 28704-9739 USA
Phone: (828) 684-4895
Fax: (828) 687-1002

CANADA Customers
Welch Allyn Canada Limited
Technical Service Center
160 Matheson Blvd., East
Mississauga, Ontario L4Z 1V4 CANADA
Phone: (416) 890-0004 or 1 800-561-8797
Fax: (416) 890-0008

INTERNATIONAL CUSTOMERS

Welch Allyn/
Speidel + Keller GmbH Co. + KG
Technical Service Center
Zollerstrasse 2-4
D-72417 Jungingen
GERMANY
Phone: 49747792710
Fax: 497477927190

Welch Allyn Australia Pty. Ltd.
Technical Service Center
Ground Floor, 18-20 Orfon Road
Lane Cove NSW 2066 AUSTRALIA
Phone: 6124183155
Fax: 6124183650

Welch Allyn Inc.
10/F., Tung Sun Commercial Centre
194-200 Lockhart Road, Wanchai,
Hong Kong
Phone: (852) 2511-3050
Fax: (852) 2511-3557

LATIN AMERICA CUSTOMERS

MDI International
Technical Service Center
7324 S.W. 48th Street
Miami, FL 33155 USA
Phone: (305) 669-9003
Fax: (305) 669-8951

The CE Mark on this product indicates it has been tested to and conforms with the provisions noted with the 93/42/EEC Medical Device Directive.

European contact for regulatory compliance:
European Regulatory Manager
Welch Allyn LTD.
Navan, Co. Meath
Republic of Ireland
Phone: 353-46-28122 Fax: 353-46-28536

VI. 2. C. SERVICE INFORMATION: SERVICE MANUAL/SPARE PARTS

A service manual is available by request to qualified electronics personnel. The service manual is a comprehensive guide to troubleshooting, service and repair of the Welch Allyn Vital Signs Monitor.

Also included with the service manual is a complete spare parts price list. Spare parts may be ordered from your local Welch Allyn Service Center.

VI. 2. D. SERVICE INFORMATION: SERVICE LOANERS

Service loaners are provided, on request, when repair service is provided by a Welch Allyn Service Center. Loaners for products repaired while under the original warranty, or while under extended warranty or service contract, are provided free of charge and are shipped within 48 hours of notification of need. Shipment charges to the user are paid by Welch Allyn.

For service repairs outside of warranty or contract, loaners will be available for a nominal daily charge and will be shipped subject to availability. Loaners will be shipped pre-paid, however this charge will be added to the service charges.

APPENDIX A - NONIN® PULSE OXIMETRY SENSORS

Warning: Only Nonin® brand SpO_2 sensors and accessories should be used with Welch Allyn Vital Signs Monitors configured with the Nonin® pulse oximetry option.

The Welch Allyn Vital Signs Monitor features a sensor which is ideal for nearly every application. These sensors include the Flex Sensor, the Fingerclip Sensor, the Ear Clip, the Reflectance Sensor and two sizes of Flexi-Form single patient use sensors. Each sensor is designed for a specific site application and specific patient size and weight range. When selecting sensors for a particular application consider the following:

1. The best performing sensor for most patients is an appropriately sized adhesive style sensor, either reusable or single patient use, located on the finger or toe.

2. The fingerclip sensor is recommended for spot checks or short term continuous monitoring. The fingerclip sensor performs best for most patients when used on fingers other than the thumb. The finger clip sensor is not recommended where motion is expected or for relatively long term monitoring; e.g. greater than 30 minutes.

3. The reflectance and ear clip sensors generally do not perform as well as sensors located on the finger or toe. They are not recommended for applications where the best possible SpO_2 accuracy is important. Use the reflectance and ear clip sensors when fingers and toes are not suitable, as with peripheral shut down, or when monitoring central body perfusion for timing response reasons. They may also be useful in high motion environments such as stress testing.

Clear Tape Strips or Hydrogel Tape Strips are recommended to provide additional securing for the reusable flex sensors.

Clean reusable sensors with an isopropyl alcohol wipe. Allow enough time for the sensor to dry thoroughly before reusing. The reusable sensors may also be sterilized using ethylene oxide (EtO) (cold cycle).

COMPATIBILITY

Caution: Use only the sensors provided by Welch Allyn. These sensors are manufactured to meet the calibration requirements for the Welch Allyn Vital Signs Monitor.

Caution: Each sensor is designed for a specific clinical application. Optimal performance can only be attained by using each sensor appropriately.

Factors that can degrade performance:

- excessive ambient light
- excessive motion
- electrosurgical interference
- arterial catheters, blood pressure, infusion lines, etc.
- moisture in the sensor
- improperly attached sensor
- incorrect sensor for patient
- poor patient perfusion
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiovascular dyes
- sensor not at heart level

Caution: Use of double backed adhesive strips or the Hydrogel tape strips should be discontinued if the patient exhibits allergic reactions to the adhesive material.

Caution: Sensor sites must be checked periodically to determine circulation, sensor positioning and skin sensitivity.

Apply the appropriate oximeter sensor per the instructions below.

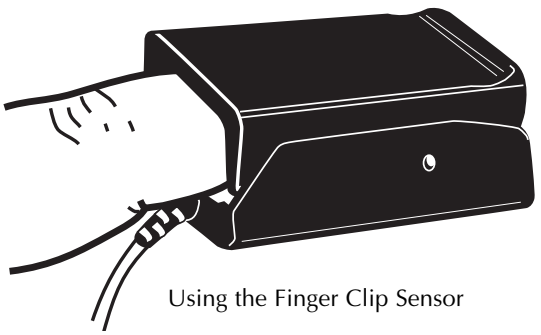
Warning: Only Nonin® brand SpO_2 sensors and accessories should be used with Welch Allyn Vital Signs Monitors configured with the Nonin® pulse oximetry option.

1. NONIN® FINGERCLIP SENSORS

The fingerclip sensor is designed for spot check monitoring of pediatric and adult patients or continuous monitoring less than 30 minutes where patient movement is not expected and the patient's finger is large enough for the sensor to be attached securely.

NOTE: If patient movement is occurring or the finger size is inappropriate, select a different sensor that is appropriate for the patient and the monitoring environment.

Insert finger (preferably left or right index finger) completely into the sensor. See illustration below. The thumb is specifically not recommended for use with the fingerclip sensor.



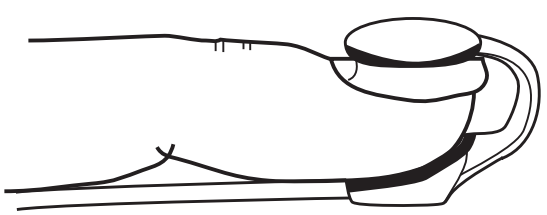
Using the Finger Clip Sensor

NOTE: For the best results, secure the sensor cable independently from the sensor, preferably around the base of the finger. Make sure that the tape securing the cable does not restrict the blood flow.

2. NONIN® FLEX SENSORS

The flex sensor is designed for monitoring of pediatric and adult patients in which moderate patient movement is expected and/or long term monitoring is required. Apply the double stick tape to the smooth side of the sensor.

Position the Sensor on the top and bottom of the end of the finger or toe. Place the light emitter portion on the finger/toe nail side and the detector on the side opposite of the nail. In all sensor placement applications, align the windows (detector and emitter portions of the sensor) over the tissue. Attach the sensor using 3M Micropore* tape, or equivalent by wrapping the tape or wrap over the sensor assembly. Wrap the sensor snug but not so tight as to restrict the blood flow. See illustration below.



Attaching the Flex Sensor

NOTE: For optimum light transmission, attach the sensor on the finger or toe. For best results, secure the cable independently from the sensor. Make sure that the tape securing the cable does not restrict the blood flow.

*Micropore is a registered trademark of the 3M Company.

3. NONIN® EAR CLIP SENSOR

This sensor is designed for adults where finger tip monitoring is impractical. Rub the ear lobe vigorously for 5 seconds and then apply the ear clip to the lobe of the ear. Make sure the ear clip is positioned so that the LED emitters and the detector are completely covered by the earlobe. This ensures no stray light bypasses the earlobe, which can lead to SpO_2 inaccuracies.

4. NONIN® REFLECTANCE SENSOR

The reflectance sensor is for use on well vascularized skin surfaces. For adults this will usually be the center of the forehead slightly above and between the eyebrows. The Reflectance Sensor Holder provides the precise pressure this sensor needs against the skin.

Remove the backing from one side of the double back tape and apply to the flange of the holder. Then remove the back from the other side of the tape. Press the sensor into the foam with the windows out, and apply to the patient. Use additional tape to secure the lead wire to the patient to avoid pulling or tipping the sensor.

Caution: The reflectance sensor is not recommended for pediatric patients because the accuracy has not been established for pediatric use.

5. NONIN® ADULT AND PEDIATRIC FINGER FLEXI-FORM SENSOR

These sensors are designed for monitoring adult and pediatric patients as a single patient use sensor and are intended for use where moderate patient movement is expected or cross contamination is possible.

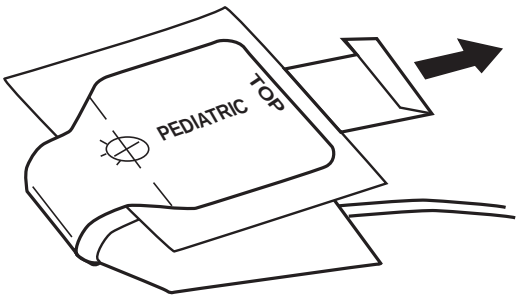
The preferred application site is the index finger. However, other fingers or toes may be used where the tissue thickness is between 5 and 21 millimeters. Other sites may not give acceptable results because of inadequate perfusion or inadequate light transmission. The application of these sensors is the same for either the adult or the pediatric patient. The difference is in the size of the sensor. For best results, secure the cable independently from the sensor. Make sure that the tape securing the cable does not restrict the blood flow.

Caution: Do not stretch the tape while applying the sensor. This may cause inaccurate readings or skin blisters.

NOTE: These sensors may be sterilized using ethylene oxide (EtO) cold cycle after removal from the plastic shipping bag.

a. Grip the tab on the sensor's bottom adhesive cover and peel the adhesive cover off.

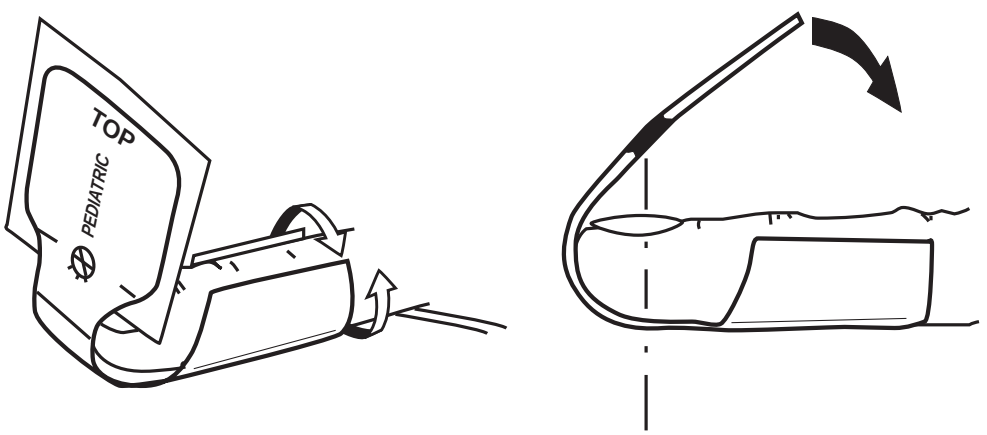
b. Place the patient's finger or toe into the sensor nail side up with the tip of the finger or toe centered against the center line mark in the curved area as illustrated. Reference the line that indicates the center of the curved area on the tape. This will assure vertical alignment between the emitter and detector. Wrap the tape around the finger. The fingernail should not be covered with tape during this step.



Attaching the Flexi-Form Sensor

c. Grip the sensor top adhesive cover and peel it off.

d. Fold the sensor's top over the top of the finger. Ensure that the detector and emitter are vertically aligned as illustrated by the dotted axis line.



Aligning the detector and emitter

APPENDIX B: NELLCOR PURITAN BENNETT™ PULSE OXIMETRY SENSORS

Warning: Only Nellcor Puritan Bennett™ brand SpO_2 sensors and accessories should be used with Welch Allyn Vital Signs Monitors configured with the Nellcor Puritan Bennett™ pulse oximetry option.

Nellcor Puritan Bennett, the leading manufacturer of pulse oximeters, offers a broad line of adhesive and reusable oximetry sensors for all monitoring requirements. This appendix contains information about selecting and applying adhesive and reusable sensors and provides tips for the optimal, cost-effective use of sensors.

Please consult the directions for use packaged with Nellcor Puritan Bennett™ sensors for additional information.

THE NELLCOR PURITAN BENNETT SENSOR FAMILY

While all pulse oximeters operate on similar principles, much of the reliability of pulse oximetry readings can be attributed to proper sensor application and fit. Nellcor Puritan Bennett offers a broad family of sensors designed to provide accurate readings on a variety of patients under a wide range of monitoring conditions.

Adhesive Sensors
Nellcor Puritan Bennett's adhesive sensors are designed to enable the sensor's light source and photodetector to be securely and properly positioned on the patient. The adhesive stabilizes these important optical components and provides a comfortable, “second-skin” fit.

Adhesive sensors are patient-dedicated and can travel with your patients. Single-patient-use sensors do not present the risk of cross-contamination caused by products that are reused from patient to patient.

Nellcor Puritan Bennett's sterile, adhesive *Oxisensor® II* sensors are the ideal choice when environmental electronic noise levels are high and the patient's pulse is weak, because special shielding in both the bandage and the cable helps protect the pulse oximetry signal. Nellcor Puritan Bennett offers *Oxisensor II* models to fit different patient sizes.

Nellcor Puritan Bennett offers another cost-effective option in its adhesive sensor line. The *OxiCliq®* system combines a reusable cable with a patient-dedicated adhesive sensor. The sensor clicks into place in the cable connector and is easy to detach when monitoring is interrupted. This two-part system is less expensive than other adhesive sensors. Nellcor Puritan Bennett offers *OxiCliq* models to fit different patient sizes.

Reusable Sensors
Nellcor Puritan Bennett also offers a broad line of reusable sensors designed to monitor various sizes of relatively immobile patients, particularly when cross-contamination is less of an issue. When short-term or intermittent monitoring is necessary, these reusable, non-sterile sensors are an effective monitoring alternative. Nellcor Puritan Bennett offers the following models of reusable sensors and accessories:

- *Durasensor*® finger clip sensor.
- *Dura-Y*® multisite sensor, which can be applied with disposable wraps, an ear clip for adults, or a pediatric spot-check clip, depending on patient size.
- *Oxiband*® sensors, applied with disposable wraps.
- RS-10 adhesive reflectance sensor.

CHOOSING A SENSOR: BASIC PRINCIPLES

The following considerations should be evaluated when choosing a sensor for your patients:

Weight
All sensors contain a light source and photodetector, which are the essential optical components necessary to determine arterial oxygen saturation by pulse oximetry (SpO_2). All Nellcor Puritan Bennett sensors are designed so that the light source and photodetector are positioned a certain distance from one another to provide for proper fit over various sizes of tissue.

Sensors should be chosen according to the patient's body weight to ensure the optical components are properly aligned when applied to the recommended area. With the exception of the reflectance (RS-10) and nasal (R-15) sensors, all sensors must be positioned so that the light source and photodetector are directly opposed to one another across an arteriolar bed (Figure 1).

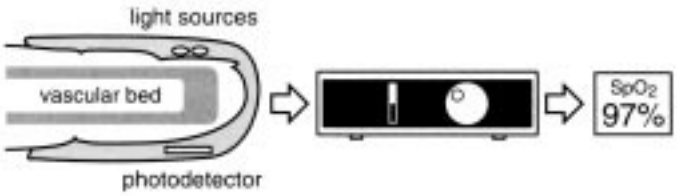


Figure 1

Duration of Use
While adhesive sensors can be used for short- or long-term monitoring, reusable sensors are generally indicated for spot-check measurements or for short-term monitoring of less than four hours. Adhesive sensor sites should be checked for skin integrity and distal circulation at least once every eight hours and changed as appropriate. Reusable sensor sites must be checked and changed at least every four hours or as specified in the directions for use.

Patient Activity
Adhesive sensors provide a stable, "second-skin" fit that maintains secure positioning of the sensor's optical components and allows the sensor to move with the patient. With active patients, these sensors provide greater monitoring reliability. Reusable sensors generally are less secure on active patients. Since the *Dura-Y* and the *Oxiband* sensors are held in place with an adhesive wrap, they provide a more secure fit on active patients than the *Durasensor* finger clip sensor.

Sterility
Adhesive *Oxisensor II* and *OxiCliq* sensors are sterile in their unopened packages. They offer an infection control advantage for patients with suspected or confirmed infections, and for those at greater risk for infection such as neonates or immunosuppressed patients.

Reusable sensors are nonsterile and require cleaning between patients with 70% alcohol or 1:10 bleach.

Monitoring Compatibility
Only Nellcor Puritan Bennett brand SpO_2 sensors and accessories should be used with Welch Allyn Vital Signs Monitors configured with the Nellcor Puritan Bennett™ pulse oximetry option.

This sensor is for use only with Nellcor Puritan Bennett instruments and with instruments that contain Nellcor Puritan Bennett oximetry or are licensed to use Nellcor Puritan Bennett sensors. Consult individual manufacturers for compatibility of particular instruments and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible for safe and effective use with each Nellcor Puritan Bennett sensor model. Because most monitoring systems manufacturers offer Nellcor Puritan Bennett sensor compatibility, many hospitals now apply an *Oxisensor II* sensor to each monitored patient. The sensor can travel with the patient from department to department throughout the hospital stay.

Latex Content
The adhesive coating of the bandage on the *Oxisensor II* sensor models I-20, I-20R, N-25 and N-25R, *OxiCliq* N, *OxiCliq* I and the ADH-A/N disposable wraps, may contain a minute amount of natural latex. Please note that this material is the same type used in commercial adhesive bandages.

With respect to the RS-10 reflectance oxygen transducer, the patient contact surface and the double-sided adhesive tabs contain no natural latex. However, natural latex is a component in the adhesive used to bond the layers within the sensor. These layers are above the patient contact surface.

The adhesive materials used in these sensors have been tested using the Latex ELISA Antigenic Protein (LEAP) Assay of Biomedical Extract testing at a nationally recognized independent testing laboratory. No latex antigen was detected in this test. The ELISA test has a lower detection threshold of 0.03 micrograms/milliliter.

TIPS FOR OPTIMAL SENSOR USE

The following considerations may facilitate reliable and cost-effective use of Nellcor Puritan Bennett sensors:

All Sensors

- Choose your sensor according to patient size, duration of use, level of activity, and infection control concerns.
- Read directions for use before using sensors.
- Many sensors have both preferred and alternative application sites, offering a broader range of placement options.
- Observe alignment marks to ensure proper position of the light source and photodetector for each sensor.
- Sensors placed on the extremities should be positioned at heart level. When selecting a sensor site, priority should be given to an extremity free from an arterial catheter, blood pressure cuff, or intravenous infusion line. This will reduce challenges related to poor pulse signals at the sensor site.
- Venous blood is usually considered nonpulsatile. Under conditions of elevated venous pressure (right-sided heart failure, tightly applied sensors, use of additional tape on the sensor, or presence of a tourniquet or restrictive dressing), peripheral venous blood may become pulsatile and could result in inaccurate SpO_2 values. To avoid inaccurate readings resulting from venous pulsations, sensors should be applied according to the directions for use.
- It is possible that light from the light source may scatter throughout edematous tissue before reaching the photodetector, which can result in inaccurate readings. Care should be taken to position the sensor on nonedematous sites.

  If extensive peripheral edema is present, the R-15 nasal sensor, RS-10 reflectance sensor, or *Dura-Y* sensor with ear clip may be an acceptable alternative.
- To reduce the potential for motion artifact on an active patient, apply the sensor or an appropriate alternative sensor to a less active, recommended site (e.g., the great toe or forehead of an adult).
- Cover the sensor site with an opaque material in the presence of bright light sources such as direct sunlight, surgical lamps, infrared warming lamps, and phototherapy lights. This will minimize the potential for ambient light interference, which can create unreliable readings.
- If peripheral perfusion makes reliable pulse signal detection difficult, consider *Oxisensor II* sensors, the RS-10 reflectance sensor, or the R-15 nasal sensor, as well as alternative sensor sites.

- Check the sensor site and circulation distal to the sensor site as specified in the directions for use.

- Exercise care when removing sensors to avoid damaging the skin.

- In cases of poor perfusion, local rewarming of sensor sites (as permitted by hospital policy) may restore adequate signal quality. Covering the sensor site with a nonconstricting bootie or glove, placing the site under a warming device, and/or correcting the cause of poor perfusion can improve blood flow to the area.

- Repositioning the patient to correct compromised blood flow may restore signal quality when readings cannot be obtained.

- Nellcor Puritan Bennett oximetry sensors should not be used during MRI scanning because the sensors could affect the MRI image, or the MRI could affect the accuracy of the oximetry measurements.

Adhesive Sensors

- Apply to clean, dry sites.

- Avoid applying additional tape over the sensor bandage. This will reduce the risk of venous pulsation and inaccurate saturation measurements as well as the potential for pressure damage at the site. However, applying tape over the cable may help prevent the sensor from becoming dislodged (Figure 2).

Figure 2

- Check sensor site and circulation distal to the sensor at least every eight hours, and change the sensor site as appropriate.

- Carefully remove the sensor from the patient for reapplication to another site.

- *Oxisensor II* and *OxiCliq* sensors may be reused on the same patient if the adhesive tape attaches without slipping. Replace the sensor when its adhesive quality is depleted.

- With *Oxisensor II* sensors, if intermittent readings are required, leave the sensor on the patient, secure the cable, and protect the site as much as possible when not monitoring.

- With *OxiCliq* sensors, if intermittent readings are required, leave the sensor on the patient and either disconnect the *OxiCliq* sensor cable (OC-3) from the sensor (Figure 3) or secure the cable with tape. Protect the site as much as possible when not monitoring.

Figure 3

- If the sensor is removed between readings, store the sensor on a clean, dry surface, such as the original sensor liner, and label with the patient's name (Figure 4).

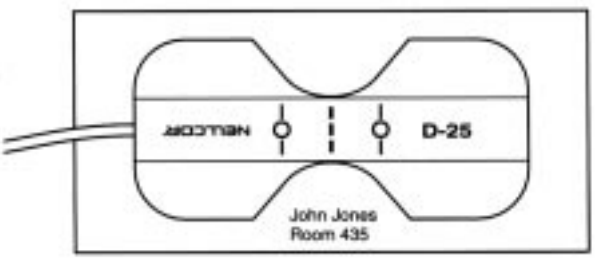


Figure 4

- Keep sensors with the patient's belongings until discharge, and notify others that the patient has a "dedicated" sensor.

- The *Oxisensor II* I-20 and N-25 and *OxiCliq* N and I sensors have six clear, double-sided adhesive "dots" that can be applied over the light source and photo detector to restore adhesive quality and extend the life of the sensor.

- In cases of poor perfusion, adhesive sensors may obtain more reliable readings than reusable sensors. The R-15 nasal sensor or RS-10 reflectance sensor may provide readings when peripheral pulse signals are poor.

- The *Oxisensor II* D-25 and D-20 sensors have an 18-inch cable, while the I-20, N-25, and D-25L come with a 36-inch cable to accommodate application in a variety of situations. The *OxiCliq* sensor cable (OC-3) is a 36-inch cable linking the *OxiCliq* sensor to the pulse oximeter.

Reusable Sensors

- Check sensor site and circulation distal to the sensor, and move the sensor to another site at least every four hours or as specified in the directions for use.
- Avoid applying additional tape to minimize the risk of impaired perfusion and tissue injury. However, applying tape over the cable may help prevent the sensor from becoming dislodged.
- Clean sensor by wiping with 70% alcohol or a 1:10 bleach solution.
- Carefully remove the adhesive wrap from the D-YS, OXI-P/I, OXI-A/N, and RS-10 to avoid damage to the patient's skin and the sensor.
- Secure the RS-10 reflectance sensor with the headband provided. Avoid use on patients in Trendelenburg, supine, or lateral positions, and with patients on mechanical ventilators.
- Apply "Do not throw away" labels to cables of reusable sensors to prevent inadvertent disposal.
- "If the cable is gray, don't throw it away": Nellcor Puritan Bennett manufactures *Durasensor*, *Oxiband*, and *Dura-Y* sensors and the EC-4, EC-8, and OC-3 cables with gray components to identify them as reusable rather than disposable items.

SENSOR ASSISTANCE FROM NELLCOR PURITAN BENNETT

Please contact the individual company representatives for specific information on the compatibility of particular instrument models with particular Nellcor Puritan Bennett sensor models.

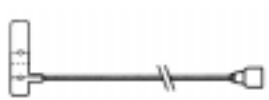
Contact your Nellcor Puritan Bennett Regional Oximetry Specialist, Account Manager, or Clinical Consultant at 1-800-NELLCOR for information and assistance with all Nellcor Puritan Bennett sensor products. They will gladly assist you, your department, and your hospital with educational presentations and any questions regarding sensors.

In addition, Nellcor Puritan Bennett's Technical Services Department provides telephone support for any questions related to sensors or other Nellcor Puritan Bennett products. Contact the Technical Services Department at 1-800-NELLCOR between 6 AM and 5 PM (PST).

Oxisensor, *Oxisensor II*, *OxiCliq*, *Durasensor*, *Dura-Y*, *Oxiband*, *Oxismart*, *PediCheck*, *C-Lock*, and the Nellcor Puritan Bennett knob configuration are trademarks of Nellcor Puritan Bennett Inc.

QUICK GUIDE FOR NELLCOR PURITAN BENNETT™ SENSORS

Oxisensor II adhesive sensors – sterile, single-patient use

MODEL	QUANTITY	APPLICATION	CHARACTERISTICS
D-25/ D-25L 	Case of 24	Adult 	• For patients who weigh ***more than*** 30 kg: - Preferred application site is index finger. - Alternative sites are thumb, smaller finger, great or second toe. • D-25 has an 18-inch cable. • D-25L has a 36-inch cable. • Check at least every 8 hours.
D-20 	Case of 24	Pediatric 	• For patients who weigh ***between*** 10 ***and*** 50 kg: - Preferred application site is index finger. - Alternative sites are thumb, smaller finger, great or second toe. • Check at least every 8 hours.
I-20 	Case of 24	Infant 	• For infants who weigh ***between*** 3 ***and*** 20 kg: - Preferred application site is great toe, with cable running along sole of foot. - Alternative site is thumb or other digit. • Use enclosed tape strip to secure cable to patient's foot or hand. • Check at least every 8 hours.
R-15 	Case of 24	Adult nasal 	• For patients who weigh ***more than*** 50 kg: - ***Only*** application site is bridge of nose. • For use in no-motion environments. • Check at least every 8 hours.

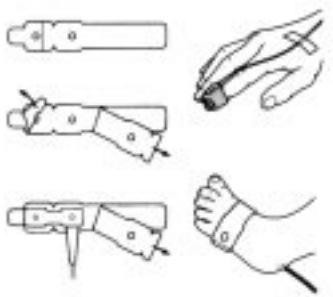
OxiCliq adhesive sensors – sterile, single patient use

A 	Case of 24 (OC-3 cable sold separately)	Adult 	• For patients who weigh ***more than*** 30 kg: - Preferred application site is index finger. - Alternative sites are thumb, smaller finger, great toe. • Must be used with *OxiCliq* OC-3 sensor cable. • Check site at least every 8 hours.

QUICK GUIDE FOR NELLCOR PURITAN BENNETT™ SENSORS

MODEL	QUANTITY	APPLICATION	CHARACTERISTICS
P	Case of 24 (OC-3 cable sold separately)	Pediatric	• For patients who weigh ***between*** 10 ***and*** 50 kg: - Preferred application site is index finger. - Alternative sites are thumb, smaller finger, great toe. • Must be used with *OxiCliq* OC-3 sensor cable. • Check site at least every 8 hours.
Dura-Y multisite reusable sensor			
D-YS	1D-YS and 40 wraps	Multisite	• **Adults** (>40 kg) - Preferred application site is index finger, with cable running along top of hand. - Alternative sites are thumb, other small finger, or great toe with cable running along sole of foot. - When using the D-YSE, alternate sites are the ear lobe and ear pinna with the cable running down the side of the patient's face and body. - Change site at least every 4 hours. • **Pediatrics** (15-40 kg) - Preferred application site is index finger, with cable running along top of hand. - Alternative sites are thumb, other small finger, or great toe with cable running along sole of foot. - For patients who weigh 30 kg or more, alternate sites are the ear lobe and ear pinna when using the D-YSE, with the cable running down the side of the patient's face and body. -Change site at least every 4 hours. • **Infants** (3-15 kg) - Preferred application site is great toe, with cable running along sole of foot. - Change site at least every 4 hours. • **Neonates** (1-3 kg) - Preferred application site is ball of foot. - Alternative site is palm of hand below the fingers, with cable running along palm. • Adhesive wraps are disposable. • Change site at least every 4 hours.
D-YSE	1 D-YSE	Ear clip (for use with D-YS sensor)	

QUICK GUIDE FOR NELLCOR PURITAN BENNETT™ SENSORS

MODEL	QUANTITY	APPLICATION	CHARACTERISTICS
PediCheck pediatric spot-check clip			
D-YSPD	1D-YSPD	Pediatric (for use with D-YS sensor)	• For patients who weigh ***between*** 3 ***and*** 40 kg: - Preferred application site is index finger or a smaller finger if it offers a better fit. • For attended, spot-check monitoring not to exceed 20 minutes of continuous application.
Oxiband reusable sensors			
OXI-A/N	1 OXI-A/N and 50 adhesive wraps	Adult/neonatal 	• **Adults** (>40 kg) - Preferred application site is index finger, with cable running along top of finger. - Alternative sites are thumb, other small finger, or great toe with cable running along sole of foot. • **Neonates** (<3 kg) - Preferred application site is ball of foot. - Alternative site is palm of hand below the fingers, with cable running along palm. • Adhesives are disposable. • Recommend changing site at least every 4 hours. • For short-term use only. If long-term monitoring is required, consider using an *Oxisensor II* D-25 or *OxiCliq* A sensor for adults and an *Oxisensor II* N-25 or *OxiCliq* N sensor for neonates.
OXI-P/I	1 OXI-P/I and 50 adhesive wraps	Pediatric/infant	• **Pediatrics** (15-40 kg) - Preferred application site is index finger, with cable running along top of finger. - Alternative sites are thumb or other small finger. • **Infants** (3-15 kg) - Preferred application site is great toe, with cable running along sole of foot. • Adhesive wraps are disposable. • Recommend changing site at least every 4 hours. • For short-term use only. If long-term monitoring is required, consider using an *Oxisensor II* D-20 or *OxiCliq* P sensor for pediatrics and an *Oxisensor II*-20 or *OxiCliq* I sensor for infants.

QUICK GUIDE FOR NELLCOR PURITAN BENNETT™ SENSORS

MODEL	QUANTITY	APPLICATION	CHARACTERISTICS
Durasensor reusable sensor			
DS-100	1 per package	Adult	• For patients who weigh ***more than*** 40 kg: - Preferred application site is index finger. - Alternative site is smaller finger. • Do not use on thumb or toe. • Recommend changing site at least every 4 hours. • For short-term use only. If long-term monitoring is required, consider using an *Oxisensor II* D-25 or an *OxiCliq* A sensor.
RS-10 reflectance sensor			
RS-10	Case of 6 sensors with 6 headbands	Adult/reflectance	• For patients who weigh ***more than*** 40 kg: - Preferred application site is forehead above the brow or below the hairline. - Alternative site is the temple. • Recommend changing site at least every 4 hours. • Use headband in brightly lit or high-motion environment. • Not for use with ventilator patients or those in Trendelenburg, supine, or lateral positions. • Limited reuse.

DS-100A DURASENSOR® ADULT OXYGEN TRANSDUCER

Nonsterile/Reusable
Directions for Use

INDICATIONS/CONTRAINDICATIONS

The *Nellcor Puritan Bennett® Durasensor®* adult oxygen transducer, model DS-1OOA, is indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing greater than 40 kg.

This sensor is for use only with *Nellcor Puritan Bennett* instruments and with instruments that contain *Nellcor Puritan Bennett* oximetry or are licensed to use *Nellcor Puritan Bennett* sensors. Consult individual manufacturers for compatibility of particular instruments and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible for safe and effective use with each *Nellcor Puritan Bennett* sensor model.

The DS-1OOA is contraindicated for use on active patients or for prolonged use. It is not designed for long-term monitoring. It must be moved every 4 hours (or more often, if indicated by circulatory status and/or skin integrity) and reapplied to a different site. If long-term monitoring is required, use an *Oxisensor® II*, oxygen transducer, model D-25, or D-25L.

INSTRUCTIONS FOR USE

Reusable sensors may be used on the same site for a maximum of 4 hours, provided the site is inspected routinely to ensure skin integrity and correct positioning. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients.

TO APPLY THE DS-1OOA:

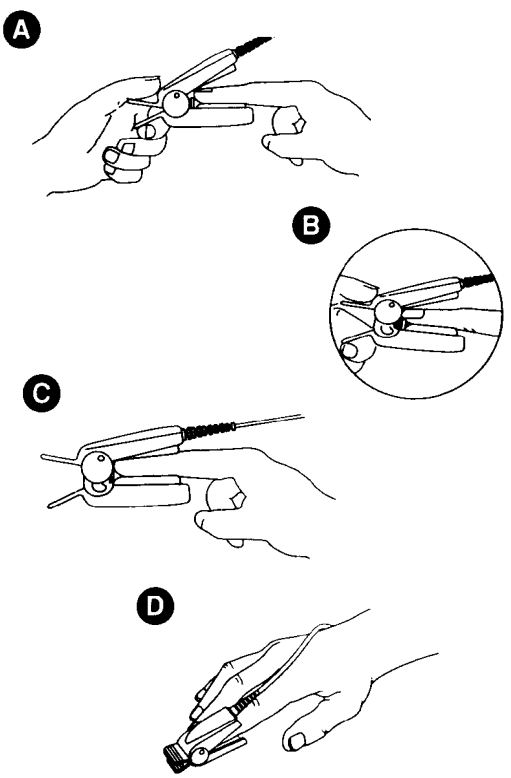
1) Place an index finger over the sensor window of the DS-1OOA with the finger tip against the stop (fig. A)

2) If the fingernail is long, the nail tip will extend over the finger stop (fig. B).

3) Spread open the rear tabs of the sensor to provide even force over the length of the pads (fig C). Check the position of the sensor. If an index finger cannot be positioned correctly or is not available, a smaller finger can be used, or use an *Oxisensor II* oxygen transducer. Do not use the DS-1OOA on a thumb or toe or across a child's hand or foot.

Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.

4) The sensor should be oriented in such a way that the cable is positioned along the top of the hand (fig.D).



5) Plug the DS-IOOA into the oximeter and verify proper operation as described in the oximeter operator's manual.

Note: If the sensor does not track the pulse reliably, it may be incorrectly positioned—or the sensor site may be too thick, thin, or deeply pigmented to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or choose an alternate *Nellcor Puritan Bennett* sensor.

CLEANING

The DS-1OOA may be surface-cleaned by wiping it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.

To clean or disinfect the sensor:

1) Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.

2) Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.

3) Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

WARNINGS

1) Failure to apply the DS-1OOA properly may cause incorrect measurements.
2) Using the DS-1OOA in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
3) Reusable sensors must be moved to a new site at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4) Intravascular dyes may lead to inaccurate measurements.
5) The performance of the DS-1OOA is compromised by motion, use of this sensor is contraindicated for active patients.
6) Do not apply tape to secure the sensor in place or to tape it shut; venous pulsations may lead to inaccurate saturation measurements.
7) As with all medical equipment, carefully route cables to reduce the possibility of patient entanglement or strangulation.
8) Do not use the DS-lOOA or other oximetry sensors during MRl scanning. Conducted current may cause burns. Also, the DS-lOOA may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
9) Do not alter or modify the DS-lOOA. Alterations or modifications may affect performance or accuracy.

If you have questions regarding any of this information, contact the Technical Services Department, or your local Nellcor representative.

WARRANTY

To obtain information about a warranty, if any, for this product, contact Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.

ACCURACY SPECIFICATIONS

For the accuracy specification range when used with *Nellcor* Puritan Bennett monitors, refer to information provided with the monitor, or (in the U.S.), contact Nellcor Puritan Bennett's Technical Services Department. Outside the U.S., contact your local Nellcor Puritan Bennett representative.

For the accuracy specification range when used with a monitor other than those manufactured by Nellcor Puritan Bennett, consult the information provided by the manufacturer of that instrument.

Note: Refer to the instrument operator's manual for complete instructions for use of the sensor with that monitor.

CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

This sensor is sold under the following U.S. Patents and foreign equivalents: 4,621,643; 4,685,464; and 4,700,708.

Oxisensor 11, and *Durasensor* are trademarks of Nellcor Puritan Bennett Inc.

APPENDIX C: WELCH ALLYN VITAL SIGNS MONITOR MOUNTING ACCESSORIES & ASSEMBLY INSTRUCTIONS

THE WELCH ALLYN VITAL SIGNS MONITOR BASKET

The mobile stand, IV pole mount and wall mount systems use the same basket.

Attaching the Monitor onto the Basket Assembly
Locate the two "keyhole" slots on the rear of the Monitor and the two circular lugs on the basket assembly, just above the basket. Insert the lugs into the large openings in the keyhole slots and slide the Monitor down until it is secured.

Removing the Monitor from the Mobile Stand
Locate the metal tab underneath and toward the back of the Monitor. With one hand in the handle on top of the Monitor, push on the metal tab and pull up on the Monitor.

Using the Wall Transformer Cord Wrap
On the side of the basket are two hooks which allow the operator to manage the transformer cord. To use the cord wrap, plug the transformer into the Monitor after installing the Monitor onto the basket assembly. Wrap the cord around the two hooks in a counterclockwise motion until there is just enough cord remaining to allow the transformer plug to rest within the basket.

THE ACCESSORY PACK

The accessory pack has the ability to be attached to the mobile stand, the wall mount, the IV pole mount or on the rear of the Welch Allyn Vital Signs Monitor. The accessory pack is easily exchangable from one mounting accessory to another using the quick-release feature. The accessory pack is designed to hold one box of temperature probe covers, a spare temperature probe or SpO_2 sensor. The accessory pack has an integrated cuff clip which can secure any of the cuffs used with the Monitor.

Attaching the Accessory Pack to the Basket
Locate the two keyhole slots on the plate on the side of the basket assembly, and the two circular lugs on the back of the accessory pack. Insert the lugs into the large openings in the keyhole slots and slide the accessory pack UP until it is secured.

Removing the Accessory Pack for the Basket
Locate the metal tab on the bottom of the accessory pack. Push the metal tab away from the basket and pull down on the accessory pack. The accessory pack will release from the basket.

Attaching and Removing the Accessory Pack from the Monitor
Use the preceeding instructions for attaching and removing the accessory pack from the basket.

Inserting the Box of Temperature Probe Covers
Open the box of 25 probe covers as directed. Insert the box into the rectangular opening beside the pocket on the Accessory Pack. The box will be tilted slightly to allow probe covers to be readily accessible when the Accessory Pack is mounted either on the basket or the Monitor.

THE MOBILE STAND

The mobile stand is designed to be rugged and durable. An integrated handle allows the stand to be easily wheeled wherever it is needed. Two of the five wheels on the mobile stand are equipped with a brake. These wheels can be identified by a lever on the outside of the wheel. The brake is engaged by pushing on one end of the lever. The brake may be released by pushing on the opposite end. For best results, use both brakes to insure that the mobile stand remains stationary.

THE IV POLE MOUNT

The IV Pole Mount kit allows the Welch Allyn Vital Signs Monitor to be attached to an IV pole with a diameter range of 0.75 inches to 1.25 inches. It is recommended that the Monitor be detached from the mounting hardware before attempting to attach or detach the pole mount to the pole. When attaching the pole mounting hardware to the pole, insure that the hardware is securely fastened to the pole before attaching the Monitor.

Welch Allyn®

Vital Signs Monitor

Mounting Accessories Assembly Instructions

Mobile Stand Kit
(Model # 5200-60 & 5200-61)

(Refer to figure 1 for the following instructions)

1) Lay BASE on floor with wheels down. Assemble POLE into BASE by inserting tapered end into hole in center of BASE. Stabilize BASE. Push down and twist on POLE until POLE is tight and two holes in the top of POLE are aligned between two adjacent legs in the BASE. Check to be sure POLE is secure. Tighten if it is not.

2) Loosen HANDLE BRACKET screws (tool provided) and slide HANDLE over pole as shown. Position approximately 10" from top of POLE. Lightly tighten screws.

3) Insert POLE CAP into the top of the POLE.

4) Assemble BASKET to BASKET PLATE by inserting (4) #8 X 3/16" long phillips screws through four holes designated "A". Securely tighten screws.

5) Assemble BASKET PLATE to POLE CAP using (1) #8 x 1/2" long phillips flat head screw inserted through top hole "B" in BASKET PLATE and into top threaded hole in POLE CAP. Do not securely tighten screw.

6) Align two "C" holes in BASKET with corresponding holes in POLE and insert (2) #8 x 1/2 long phillips screws. Securely tighten these screws and screw assembled in step 5.

7) Loosen HANDLE BRACKET screws again and slide HANDLE up under basket to desired height and location. Securely tighten screws.

8) *For Model #5200-60 only*, attach ACCESSORY PACK by orienting as shown in figure 1 and inserting onto side plate of BASKET and pushing up. This will lock ACCESSORY PACK onto BASKET.

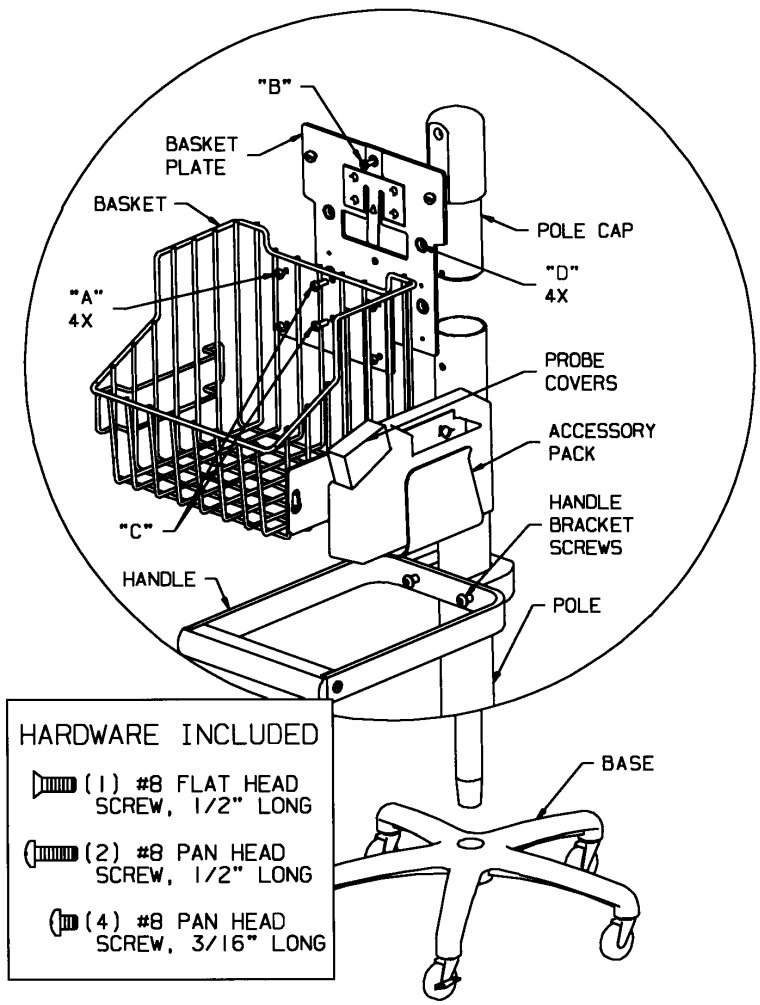


Figure 1

Wall Mount Kit (Model # 5200-62 & 5200-63)

(Refer to figure 2 for the following instructions)

1) Attach BASKET PLATE to wall by inserting (5) #8 flat head screws (not provided) through BASKET PLATE in four "D" holes and one "B" hole. Securely tighten screws.

NOTE: Mounting hardware should be selected according to the wall surface that monitor is being attached to. Welch Allyn is NOT responsible for the integrity of the mounting means. If there is any indecision or uncertainty on what hardware to use, contact a professional service for installation.

2) Assemble BASKET to BASKET PLATE by inserting (4) #8 X 3/16" long phillips screws through basket holes marked "A" and into four threaded holes in BASKET PLATE. Securely tighten screws.

3) *For Model #5200-62 only*, attach ACCESSORY PACK by orienting as shown in figure 2 and inserting onto side plate of BASKET and pushing up. This will lock ACCESSORY PACK onto BASKET.

I.V. Pole Kit (Model # 5200-64 & 5200-65)

(Refer to figure 2 for the following instructions)

1) Attach BASKET PLATE to I.V. BRACKET by inserting (4) #8 X 1/4" long flat head phillips screws through four countersunk holes, designated "D", into four threaded holes in bracket. Securely tighten screws.

2) Assemble BASKET to BASKET PLATE by inserting (4) #8 X 3/16" long phillips screws through basket holes marked "A" and into four threaded holes in BASKET PLATE. Securely tighten screws.

3) *For Model #5200-64 only*, attach ACCESSORY PACK by orienting as shown in figure 2 and inserting onto side plate of BASKET and pushing up. This will lock ACCESSORY PACK onto BASKET.

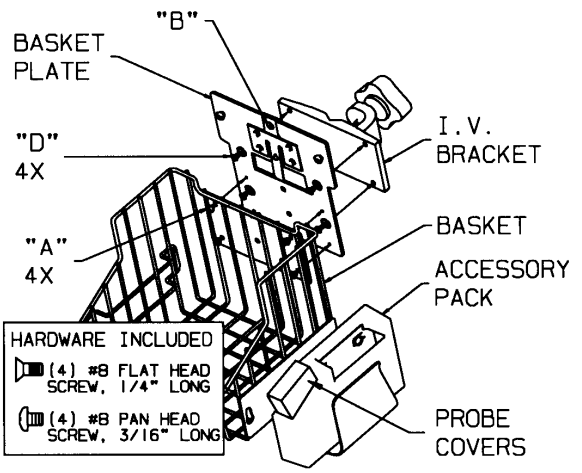


Figure 2

Bedrail Kit (Model # 5200-66 & 5200-67)

(Refer to figure 3 for the following instructions)

1) Remove top two housing screws on one side of MONITOR only.

2) Orient BEDRAIL as shown and attach using (2) #4 x 1-1/8" long screws supplied. Securely tighten screws.

3) Repeat steps 1 & 2 on other side of MONITOR.

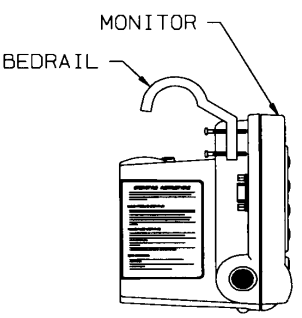


Figure 3

Instruction Sheet P/N: 95P374 (3/14/97)

ART9807-E

Vital Signs Monitor

Anti-theft Kit Installation Instructions

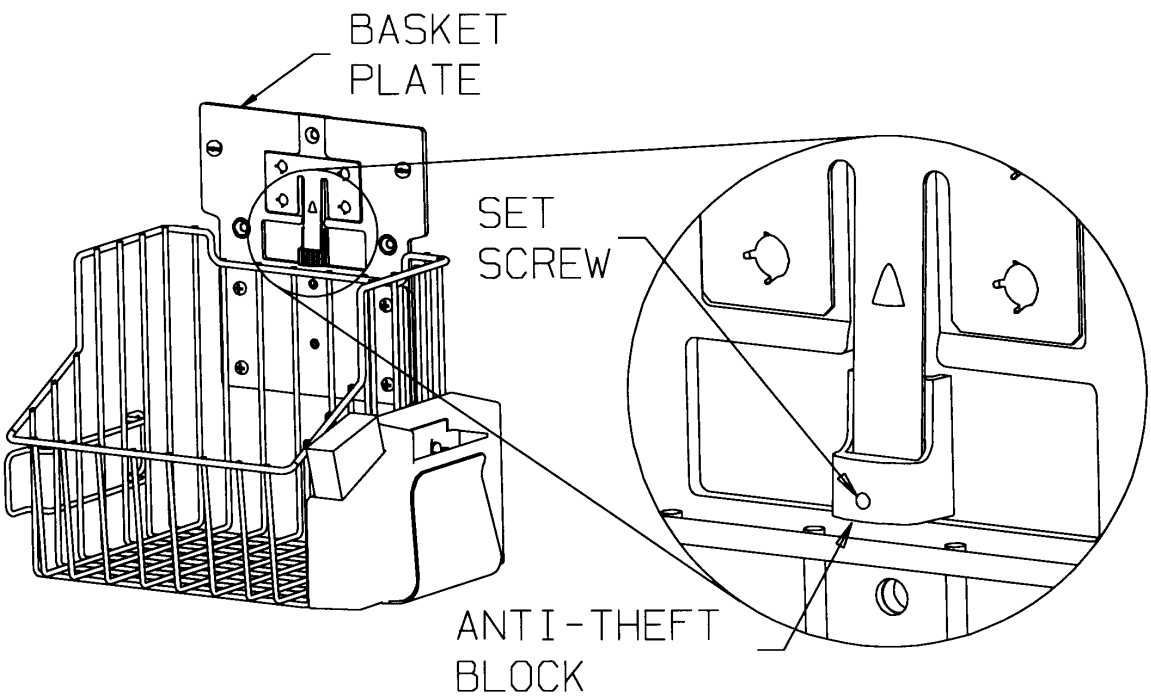
Anti-theft Kit (Model # 5200-70)

1) With monitor detached, assemble ANTI-THEFT BLOCK onto tab on BASKET PLATE oriented as shown below. Allow ANTI-THEFT BLOCK to rest freely as shown. Do not tighten SET SCREW.

2) Attach monitor to BASKET PLATE.

3) Slide ANTI-THEFT BLOCK up until it seats against bottom of monitor. With allen wrench provided, tighten SET SCREW to secure ANTI-THEFT BLOCK to tab.

4) Retain allen wrench for future use.



Instruction Sheet P/N: 95P375 (3/14/97) ART9808-E

Welch Allyn®

Vital Signs Monitor

Transformer Mounting Instructions

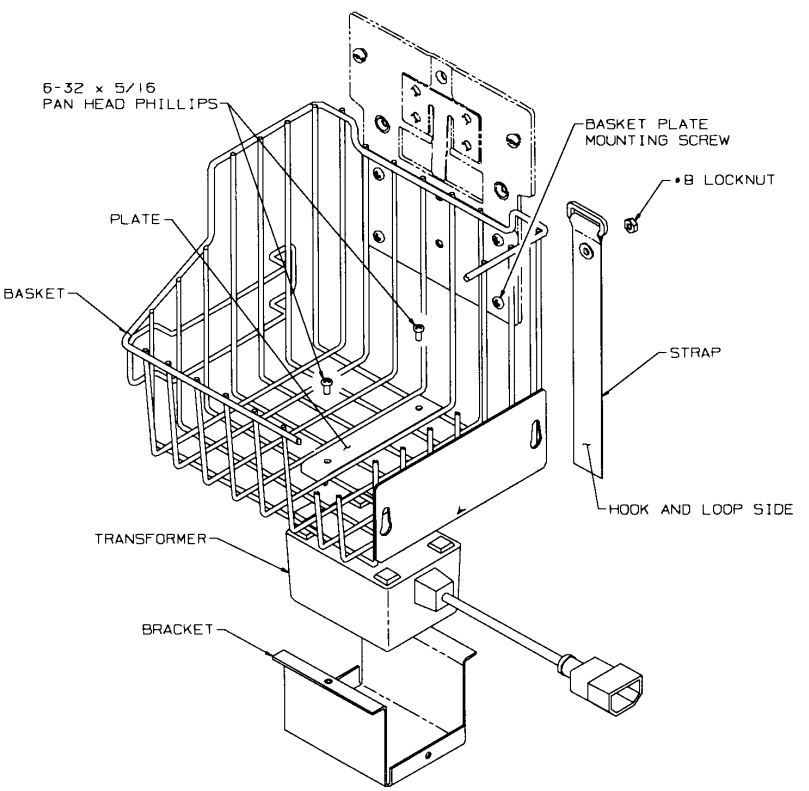
Transformer Mounting Kit (Model #5200-106)

1) Position PLATE in basket as shown.

2) Place TRANSFORMER in BRACKET. With transformer oriented as shown, secure bracket to plate using (2) # 6x 5/16" long pan head phillips screws. Tighten screws to prevent transformer movement.

3) Remove basket plate mounting screw indicated and replace with # 8-32 x 1/2" long pan head phillips screw. Tighten securely.

4) Place STRAP over basket plate mounting screw in basket plate with hook and loop side towards basket. Secure with # 8 LOCKNUT.



Instruction Sheet P/N: 95P395 (12/06/96) ART9859

Welch Allyn Vital Signs Monitor _____
Serial Number:

Date of Purchase:_____

Dealer Name: _____

Telephone:_____

Dealer Representative Name:_____

Telephone:_____

Welch Allyn
Sales Representative: _____

Welch Allyn Vital Signs Monitor Operator's Manual
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